The association between health anxiety and psychological adjustment in patients undergoing stoma surgery

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To Sebastian & James

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ABSTRACT

Stoma surgery is challenging and has been found to impact body image, social relationships including sexuality, health-related and general quality of life. Some patients exhibit negative affect and struggle to adjust to living with a stoma. Stoma care nursing and the self-efficacy beliefs appear to be protective factors for adaptation in this patient group. Health anxiety seems highly prevalent in medical health conditions but has not yet been investigated in a stoma patient population.

The aim of the current study was to investigate the role of health anxiety in the adjustment to stoma in patients undergoing emergency or planned surgery. Health anxiety was also examined as mediator for the relationship between stoma self-efficacy and stoma adjustment. A further aim was to explore psychological differences (i.e. health anxiety, self-efficacy, adjustment, overall distress, preparedness for surgery) in the two patient groups that were included in this study (i.e. emergency versus planned stoma operation).

The study used a cross-sectional design and patients were assessed using valid and reliable self-report measures. Patients were recruited from one NHS hospital setting and internet-based sources such as websites and support groups.

The results show that health anxiety is associated with poorer adjustment. Patients who are highly health anxious appear to adjust less well to living with a stoma. The protective impact stoma self-efficacy has on adjustment, as demonstrated in previous studies, was replicated. In addition, the current study shows that the positive relationship between self-efficacy and adjustment is

negatively impacted by health anxiety. A further finding of this study is that emergency and planned surgery patients do not differ on psychological variables including health anxiety, distress, self-efficacy and adjustment.

The study has offered valuable insight in the processes that are involved in the adjustment process after stoma surgery. It is proposed that patients with clinical levels of health anxiety may benefit from psychological therapy focusing on health anxiety before they can adaptively engage in the journey of helpful coping and adjustment to living with their stoma. Adjustment is a complex and fluid process and future research should endeavour to investigate how pre-operative psychological factors influence how patients cope after their surgery.

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CHAPTER 1: INTRODUCTION

This chapter will introduce the topics of this thesis and provide the reader with the relevant background knowledge and existing literature that is of importance in the context of this thesis. Firstly, this chapter will outline the medical aspects of stoma surgery. This will be followed by a description of the relevant literature in respect of the impact of surgery that results in a stoma, and the impact of living with a stoma on the well-being and quality of life for patients. At the end of this chapter, the relevant concepts of health anxiety and self-efficacy will be discussed against the background of the existing literature presented. This will lead to a presentation of the current study, which aimed to further extend the knowledge about stoma patients and their challenges with anxiety and coping.

INTRODUCTION TO THE MEDICAL UNDERPINNING OF THE STUDY

What is a stoma?

'Stoma' is an umbrella term for a specific form of surgery dealing with the creation of a new opening for parts of the digestive or urinary system. The opening of these systems might be necessary to prevent serious medical complications or even the death of a patient (Saunders & Hemingway, 2008). In short, the surgery involves a procedure in which parts of the affected tissue are removed and a passage is created through the abdominal wall. This passage is formed using the healthy parts of the digestive or urinary system and redirects the excretion of those systems, which is contained in an external bag called stoma bag.

A *colostomy* is the most common type of stoma and can be a result of having surgical treatment for colorectal cancer or cancer of the anus (White, 2010). A colostomy is an opening made during surgery in which the large intestine is brought to the surface of the abdomen and is usually situated just below the umbilicus. The patient may experience phantom sensations of normal bowel movements after the operation, which can be distressing if they are not prepared for it (White, 2010). Colostomies can be of temporary nature and this is the case when the main reason for the operation was it to give the healthy part of the digestive system time to heal. After the healing process is complete, healthy parts of the system are re-joined and normal function can be resumed for most individuals (White, 2010).

An *ileostomy* is similar to a colostomy but situated in a different part of the body. It is created during surgery by bringing the small intestine to the surface of the abdomen. The different placement of the ileostomy, which is attached to the digestive system (i.e. so higher up as compared to the colostomy bag), results in waste material, which contains more water and digestive enzymes that are harmful to the skin and can cause irritation (White, 2010). Ileostomies can also be temporary or permanent.

Urostomies are surgically formed openings for patients who suffered from bladder cancer and for whom the bladder needs to be removed (White, 2010).

Medical diagnosis associated with stoma surgery

Patients may suffer from various conditions prior their stoma surgery, these include Crohn's disease, bladder cancer, colorectal cancer ("bowel cancer"),

familial polyposis coli, diverticular, cancer of the anus, and ulcerative colitis (Salter, 1997; White, 2010). Bowel cancer is also the most common condition patients with a stoma suffer(ed) from (CancerResearchUK, 2014). The onset of this cancer is usually gradual and symptoms may not occur until later stages of the cancer; symptoms most commonly include bleeding from the anus and rectum (White, 2010).

Prevalence

Each year in the UK, approximately 13,500 people undergo elective or emergency surgery that result in a stoma (Baxter & Salter, 2000). Worldwide, the 5-year prevalence rate for bowel cancer (one of the most common illnesses leading to stoma surgery) is estimated at over 3.5 million incidences (IARC_GLOBOCAN, 2012). It is the third most common cancer in men and second most common cancer in women with the highest estimated rates in Australia and New Zealand and lowest estimated rates in Western Africa (IARC_GLOBOCAN, 2012). However, it appears that because of improvements in screening for this type of cancer and its treatment, mortality rates decline and fewer patients now die within the first 5 years of their diagnosis (American_Cancer_Society, 2015).

The corollary of this being that patients with this cancer diagnosis are expected to live longer, due to treatments including stoma surgery, which has triggered research about the quality of life (Gavaruzzi et al., 2014; Kement et al., 2014) and adjustment in stoma patients (Simmons, Smith, Bobb, & Liles, 2007; Simmons, Smith, & Maekawa, 2009). Although in many cases stoma surgery is

lifesaving, it seems to be associated with challenges to both physical and psychological functioning (Brown & Randle, 2005).

Managing a stoma

Living with a stoma can have profound consequences for the individual and impact on their mood, body image, relationships and their work life (CancerResearchUK, 2014).

Post-surgery, patients are introduced to a variety of aspects about how to manage their stoma when they return home. This involves getting familiar with stoma care appliances such as a one-piece stoma bag, two-piece stoma bag, drainable stoma care appliances, and closed stoma care appliances. Patients need to learn how to change their stoma bag and how to empty the waste material; how to deal with leakage, the smell and noise of a stoma bag (White, 2010).

It is common that patients worry about these aspects and experience anxiety in regards to handling these challenges, especially in public (Gray, Blackinton, & White, 2006; White, 2010). Embarrassment is not uncommon in this population (Mrak, Jagoditsch, Eberl, Klingler, & Tschmelitsch, 2011) and patients may engage in behaviours that are likely to maintain a vicious cycle of anxiety and avoidance strategies (White, 2010).

For example, it might be that patients adjust their lifestyle as a consequence by avoiding extended periods in public, not going on holiday, planning outings in great detail, or they might avoid social contacts all together. Research has shown that social support is fundamental to the quality of life of cancer patients and that it can be a strong buffer against the adversity this illness can have on patients'

psychological functioning (Nausheen, Gidron, Peveler, & Moss-Morris, 2009; Paterson, Robertson, & Nabi, 2015; Salles, Becker, & Faria, 2014).

Impact of stoma on patients

The following review of the literature is concerned with research investigating variables that have been found to impact on stoma patients.

Adverse effects of stoma surgery on body image

Ostonomy surgery is invasive and leaves patients with visible signs to their body, i.e. the stoma bag on the outside of their abdomen. Western society places immense importance on the attractiveness of bodily appearance (Salter, 1997). Given the invasive nature of the operation, body image, which can be defined as the perception of one's physical appearance (Jenks, Morin, & Tomaselli, 1997), has been investigated in the context of ostonomy surgery and linked to distress in patients (Sharpe, Patel, & Clarke, 2011).

Women, more often than men, have been reported to perceive stoma surgery as particularly negative for body image (Nordstrom & Nyman, 1991). A qualitative interview study with seven participants by Salter (1992d) described themes including disgust, embarrassment, shock, hate, repulsion, devastation, and unacceptance in patients with a conventional stoma. Within this sample, three patients' stoma had been temporary and they underwent revision of their stoma into a continence pouch. These participants reported that they felt more 'normal' after the revision and had improved body image. The results of this study should be considered with caution as all participants attended a clinic due

to problems with their stoma. Hence, this sample may not represent the population.

Jenks et al. (1997) conducted a study with 45 individuals, aged between 30 and 80, who were undergoing colostomy surgery after receiving a cancer diagnosis. They measured body image at three different points: before the operation, 1 month, and 6 months post-operatively using validated instruments. Moreover, qualitative interviews were conducted. Findings indicated that body image perception was lowest prior to surgery suggesting that the cancer diagnosis and the prospect of having colostomy surgery negatively impacted on body image. This was further supported by their qualitative results, which implied that the level of uncertainty and hopelessness was most prominent before surgery. The authors concluded from their results that negative body image improves as length of time from surgery increases.

Impact on sexuality and intimate relationships

Closely linked to body image is sexuality and many patients with stoma worry about this aspect of their lives (Nordstrom & Nyman, 1991; Persson & Hellström, 2002; Salter, 1992a). Research suggests that patients perceive themselves as less sexually attractive despite reassurance by their partners (Salter, 1992a, 1992d). Nugent (1999) found that over 40 % of patients report problems with their sex life. It appears that some men experience erectile problems post-surgery and women were reported to have decreased or no sexual activity after their stoma surgery (Nordstrom & Nyman, 1991).

The before mentioned study by Nugent (1999) was conducted to assess quality of life retrospectively in a large sample of almost 400 participants. The authors of the study concluded from their analysis of the self-report measures that, although many patients adjust well to a life with a stoma, some patients experience considerable distress. This was mainly related to pre-operative preparation of patients and follow-up treatment (i.e. counselling after the surgery). Patients who received appropriate support, adjusted better. Although this study was based on a large sample, it bears at least two crucial problems. The research appears to be based on self-report measures that were not validated for this patient group. Moreover, participants were encouraged to answer questions retrospectively and for some patients that meant thinking about a surgery that had taken place almost 40 years ago. Hence, there was a risk of considerable bias because of memory effects in this study.

Quality of life of stoma patients

Summarising the various aspects of how social, individual, and occupational life can be impacted by the stoma, the impact of living with a stoma on quality of life has been investigated in other studies. Persson et al. (2002) used a qualitative approach in a Swedish sample and interviewed men and women between 6 weeks and 3 months after their operation. They identified several themes relating to; feelings of detachment from the body, body image disturbances, impaired sexual life and relationships, decrease in leisure and physical activities, and adverse impact on the social life of these patients. Using a similar study design, Nordstrom (1991) found that physical problems with the stoma were seen as the major factor influencing the quality of life negatively.

These themes are repeatedly found in studies involving a stoma population (Orsini et al., 2013; Salles et al., 2014; Salomé, de Almeida, & Silveira, 2014; Taylor & Morgan, 2011). In addition, Liao (2014) discussed the potential influence hope might have on stoma patients, in work, social functioning and quality of life. This study may have benefitted from including a measure assessing anxiety and depression, which are likely to be linked to hope(lessness) (Miller & Seligman, 1975; Seligman, 1972) to further explore the construct of hope and its relationship to functioning.

Negative cognitions and beliefs and their influence on distress

It appears that the quality of life of patients with a stoma can be impaired and indeed some patients exhibit psychological problems such as distress, concerns and negative cognitions (White, 1998; White & Unwin, 1998), and lack of self-confidence (Foulis & Mayberry, 1990). White et al. (1998) carried out a cross-sectional study with 79 patients who had undergone stoma surgery within a period of one to three months prior to their assessment. They were asked to complete the Stoma Cognitions Questionnaire (SCQ), a questionnaire the team had developed for the purpose of the study. The SCQ measures beliefs about stoma related cognitions. Further, distress and physical symptoms were assessed, and demographics data and information about the operation were collected. Using stepwise multiple regression analysis, the findings suggested that three of the SCQ items explained 58 % of variance in psychological distress. It also appears that the remaining 10 items of this self-report measure did not contribute to the explanation of variability amongst scores. It is noteworthy that the item, “I am still a complete person despite my stoma” accounted for 44 % in

overall variance suggesting that this single item is of profound significance in the context of psychological distress in stoma patients. Although the scale is reported to have a Cronbach's alpha of .90, suggesting high internal consistency, the results of this study indicate that not all items are in fact of predictive value for distress in stoma patients despite its development for this purpose. There is very little information to further understand the development of the scale in this study and the authors neglect to discuss this aspect of their results any further.

In addition to the aforementioned SCQ items, a history of mental health problems and pronounced physical symptoms were also significant factors in the regression model for psychological distress. Thus, the authors concluded from the results that a past psychiatric history in combination with complicated physical symptomatology after surgery is related to psychological distress in patients.

Negative cognitions about the stoma such as physical integrity, impact on life, and sense of control were discussed as contributing factors for adjustment in stoma patients. Other research has also found an association between previous psychiatric history and post-operative complications and maladjustment (Thomas, Madden, & Jehu, 1987a, 1987c; Thomas, Turner, & Madden, 1988).

The above study by White et al. helps to understand how patients' negative belief system may be related to struggling to cope after surgery; however, the way psychological adjustment was measured, i.e. using the Hospital Anxiety and Depression Scale, at one point in time after surgery is potentially a shortcoming of this study. Firstly, it remains unclear how distress levels prior to surgery may

have impacted on how patients experienced the operation and their ability to adjust to changing life circumstances post-surgery. Although information about past mental health problems were collected in the form of self-reports, it would have been an advantage to measure depression and anxiety pre-surgery to be able to compare score with post-surgery levels. More importantly, the scale used for measuring adjustment is somewhat unspecific given that there are inventories now available that measure adjustment for the specific circumstances of stoma patients (i.e the Ostonomy Adjustment Inventory, (Simmons et al., 2009)).

However, notwithstanding these observations, this study is in line with research suggesting that cognitive factors play an important part in how patients cope after stoma surgery. Bekkers et al. (1997) followed stoma patients for 4 years and compared psychological adjustment in 59 stoma patients with a control group of 64 patients undergoing bowel resection (non-stoma surgery) . The Psychosocial Adjustment to Illness Scale (PAIS-SR) was used to assess vocational environment, domestic impairment, sexual relationships, social environment, and psychological distress in this sample. Both groups were found to experience a similar level of psychosocial problems four years after surgery and the stoma did not appear to make a difference. Interestingly, income had a significant impact on adjustment score with lower levels correlated with overall poorer adjustment in patients. Moreover, patients with low adjustment scores shortly after surgery were more likely to drop out of the study due to death or terminal status of their illness. Other research has also found a link between the socioeconomic status of patients and psychological adjustment in the context of

medical interventions (Simon, Steptoe, & Wardle, 2005). The authors explain the link with higher prevalence of depression and anxiety in individuals, which impacts on their ability to cope with stresses and demands of surgery.

Stoma care and nursing

Research has shown that pre-operative preparation and the advice given to patients impacts on their coping post-surgery (Metcalf, 1999; Thomas et al., 1987c). Metcalf (1999) found that by teaching stoma patients practical skills such as: considering nutritional needs and impact on digestion, taking care of the stoma bag, organising outings and travel, and communicating to others about the stoma, then patients felt empowered and more able to manage their stoma and aspects of their life.

Patients value the pre-operative care provided by nurses (Worster & Holmes, 2008) and benefit from nurse-led telephone follow up programmes helping patients to adjust after their cancer diagnosis and the invasive treatment for it (Zheng, Zhang, Qin, Fang, & Wu, 2013).

Wroe et al. (2003) conducted a study with 117 participants, who were treated with anti-HIV medication and found similar results. The participants were asked about their adherence to the treatment protocol using a self-report measure. The authors found that, amongst other factors, intentional non-adherence was inversely related to the extent to which participants felt prepared for the side effects of the medication by the clinical team.

These results also show that patients seem to benefit from feeling that they have knowledge about their medical treatment by asserting their control over

their situation and by having time to cognitively adjust to what might be expected in their near future from their treatment.

Differences between patients undergoing emergency versus planned surgery

Previous research investigating differences between emergency and planned cancer surgery patients has been published in medical journals. Thus, it seems that the main focus in research was put on prognostic factors and the physical response in patients after different types of surgery.

Emergency surgery for colorectal cancer is, in most cases related to an advanced stage of the disease and has been found to be a poor prognostic factor associated with a more aggressive tumour presentation. This often results in longer surgeries and admissions and more frequent readmissions. This has a significant impact on health care costs (Amri, Bordeianou, Sylla, & Berger, 2015). Higher mortality rates for patients undergoing emergency surgery for colorectal cancer have been found in other research (Dekker et al., 2014; Santos et al., 2014).

Elderly patients and patients with higher levels of frailty have particularly less favourable prognostic outcomes (Kenig & Richter, 2013; Kenig, Zychiewicz, Olszewska, & Richter, 2015). A comprehensive review, including 28 independent studies, found that although there seems to be a relationship between age and outcomes from colorectal cancer surgery, prognosis and mortality is also associated with stage of illness, pre-existing comorbidities and emergency surgeries (Simmonds et al., 2000).

ADJUSTMENT IN STOMA PATIENTS

Research suggests that stoma surgery can have a profound impact on patients and influences almost all aspects of their lives, often in an adverse way. Depression and anxiety, loneliness, and low self-esteem are often found in this population (Sprangers, Taal, Aaronson, & Tevelde, 1995) and research suggests that patients struggle to adjust to the stoma (Vironen, Kairaluoma, Aalto, & Kellokumpu, 2006), especially in the absence of supportive relationships (Giese-Davis, Hermanson, Koopman, Weibel, & Spiegel, 2000).

Meeting the needs of patients and understanding the determinants of maladjustment and psychological adversity are therefore crucial and require an understanding of the nature of mental health problems in the affected group within the stoma patient population.

Before discussing the literature about adjustment in stoma patients, theoretical and conceptual underpinnings of the construct of psychological adjustment are described.

Definitions of adjustment

The Oxford Dictionary (*Oxford Dictionary of English*, 2010) defines adjustment as a "process of adapting or becoming used to a new situation". Thus, psychological adjustment encompasses a complex variety of psychological processes and elements such as cognitive, affective, behavioural, and social factors.

Adjustment can be seen as an on-going process that may result in someone adjusting to the novelty of their circumstances by showing adaptive cognitions, emotions, and behaviours (Chilcot & Moss-Morris, 2013).

Stress-coping model

The stress-coping model of Lazarus and Folkman (1984), a frequently used model in the context of psychosocial adjustment to chronic illness, describes how adaptation in the face of challenges is influenced by a person's evaluation and appraisal of the stressors on the one hand, and the coping strategies they feel able to use, on the other hand. These appraisals involve the interpretation of the sources of stress in terms of threat, challenge, and controllability.

Processes of adjustment require coping strategies and the authors define those as conscious efforts of a person to manage internal or external stressors (Lazarus, 2006). Coping is mostly categorised into emotion-focussed and problem-focussed strategies, whereby emotion-focussed coping aims to decrease the distress caused by the stressor, and problem-focussed coping attempts to alter the source of stress (Lazarus, 2006; Lazarus & Folkman, 1984).

What can we learn about adjustment from other illnesses?

The previous section showed that adjustment is a complex and fluid construct that is used as an overarching term to describe how individuals cope with, and adapt to, stressors such as physical illness.

Dennison et al. (2009) reviewed the literature around adjustment in patients with Multiple Sclerosis (MS) and summarised their findings in a working model to suggest different factors that seem to be related to successful and ineffective

adjustment. Using a cognitive behavioural approach, the authors propose that a critical event such as being diagnosed with MS, having a relapse, or experiencing a progression of symptoms is influenced by personality, by early experience, and their associated core beliefs, values, and behaviours. This, in turn, will determine to what extent and how a person's functioning is challenged. The review of the existing literature in MS found that successful adjustment and ineffective adjustment were associated with the following factors, summarised in Table 1.

Table 1 Model of adjustment in multiple sclerosis (adapted from (Dennison et al., 2009)

SUCCESSFUL ADJUSTMENT	INEFFECTIVE ADJUSTMENT
<u>Cognitive factors:</u> • Using positive re-appraisal • Perceived control over situation • Self-efficacy regarding symptoms management / generic life situations • Optimism • Hope • Benefit finding • Acceptance of illness • Spirituality <u>Behavioural factors</u>: • Coping by using problem-focussed approach or seeking social support • Health behaviour <u>Social factors</u>: • High perceived social support • Positive relationships within family	<u>Cognitive factors:</u> • High perceived stress • Coping through wishful thinking or avoidance • Uncertainty about illness • Appraisal of illness as threatening • Dysfunctional cognitions (i.e. distortions, biases) • Perceived barrier for health behaviour • Unhelpful illness representation • Unhelpful beliefs about symptoms <u>Behavioural factors</u>: • Coping through avoidance • Unhelpful response to symptoms (i.e. avoidance)

The review showed that there is strong to moderate evidence for a variety of modifiable variables that are related to how patients adapt to physical illness. It shows that cognitive and behavioural avoidance are likely to increase maladaptation in patients. Illness perception and the unhelpful appraisal of symptoms are further determinants that may lead to ineffective adjustment. This has also been found in other research involving a population with MS. In a study with 168 patients, illness representations were the most significant predictor for social dysfunction, anxiety, and depression, fatigue and low self-esteem (Jopson & Moss-Morris, 2003).

In cancer populations, research has found positive associations between personality factors such as personality D (distressed) and heightened and clinically significant illness perceptions (Mols, Denollet, Kaptein, Reemst, & Thong, 2012). In comparison with patients who did not fit this personality type, patients with personality D believed their illness has more serious consequences, worried more about their diagnosis and experienced more symptoms that they attributed to their illness. This study, using a large, population-based design with almost 4000 participants (N = 750 personality type D) provided strong evidence for the link between anxiety and emotional malfunctioning and adverse outcomes in a population of cancer patients.

Illness perception (i.e. comprehension of disease, controllability of illness, cause of illness attributed to internal factors) was also found to be associated with poor emotional well-being (Traeger et al., 2009), and as predictor for

negative affect and psychological distress (Dempster et al., 2011; Herkommer et al., 2012).

A study investigating psychological morbidity (measured with General Health Questionnaire – 28) in a prospective sample of 371 women who had breast cancer surgery found that patients with clinically significant and remaining levels of distress over a period of 12 months post-surgery had higher levels of symptom awareness and poorer self-rated health (Millar, Purushotham, McLatchie, George, & Murray, 2005). They also found that the level of distress immediately after surgery was predictive of general quality of life and adjustment.

Chronicity of illness can be a strong contributor to maladjustment. A study with patients suffering from Crohn's Disease suggest that health related quality of life is predicted by levels of self-perceived health and perceived consequences of the illness (van der Have et al., 2013). In palliative care, illness perceptions were linked to adjustment to the illness and psychological distress in patients (Price et al., 2012).

EMOTIONAL FUNCTIONING AS A PREDICTIVE FACTOR FOR ADJUSTMENT IN STOMA PATIENTS

In the beginning of this chapter, research impacting on adjustment in stoma patients was introduced and showed that individual, interpersonal, and social aspects of stoma patients' life can be profoundly tested. The research described in the last sections of this chapter goes on to provide evidence for an association between adjustment in chronically ill patients and the way they perceive their illness, health, and the extent to which they control their disorder.

Stoma surgery appears to confront patients with fundamental challenges. The existing body of knowledge suggests that mental health problems including anxiety disorders and maladaptive illness perception might impact on the ability to adjust to the multifaceted challenges patients are confronted with after their stoma operation (Gavaruzzi et al., 2014; Graça P., Figueiredo, & Fincham, 2012; Millar et al., 2005; van der Have et al., 2013). Research has shown that personality traits such as neuroticism, anxiety, and obsessionality can impact on living well with a stoma (Thomas et al., 1987c).

What are anxiety disorders?

Anxiety is an emotional state that is linked to cognitive, behavioural, and physical processes. Common anxiety disorders include panic disorder, health anxiety, social phobia, PTSD, and generalised anxiety disorder.

Clark (1999) describes six processes that are likely to maintain anxiety-related negative cognitions.

- *Safety seeking behaviours* (Salkovskis, 1996a) are actions performed to prevent or minimise expected negative outcomes. A socially phobic patient might avoid giving an oral presentation to prevent his feared worst-case scenario. Inadvertently, the avoidant behaviour is also preventing this person from gaining evidence that their prediction might be wrong (Clark, 1999).
- *Attentional deployment* – both the selective attention towards and away from threat cues – is likely to maintain anxiety symptoms by enhancing the perception of threat.

- Clark also discusses *spontaneously occurring mental images* of fears, which are common in various anxiety disorders and are related to enhancing the perception of threat.
- There are patients who have been found to use perceived bodily sensations as a source for evaluating the level of their anxiety. These physical arousal symptoms, common in anxiety disorders, may lead to a heightened perception of anxious feelings. These processes have been called *"emotional reasoning"* (Arntz, Rauner, & Van den Hout, 1995).
- Lastly, Clark (1999) describes two *memory processes* that may contribute to the perpetuation of anxiety symptoms. One is the tendency for anxious patients to select information that confirms their worst-case scenario. Secondly, memory biases in respect of recall and priming, common in Post-Traumatic Stress Disorder (PTSD), have been linked to maintenance processes in anxiety disorders.

Salkovskis (1996c) describes two main factors that are involved in the development and maintenance of anxiety disorders. This model helps to understand the links between appraisal and emotional functioning and the linkages with the stress-coping model described above.

One factor involved in the perpetuation of anxiety symptomatology relates to the extent to which anxiety is experienced. On the one hand, the degree of anxiety experienced is related to assumptions about of how to deal with stressful and anxious feelings and their meaning (i.e. "I must always stay calm." "If I don't

control my feelings, something awful will happen."). These are developed throughout life and impact on how stressors are interpreted as dangerous and threatening. On the other hand, anxiety is influenced by how the threat itself is evaluated. Salkovskis (1996c) proposed a model in which he includes the following elements.

$$\text{Anxiety} = \frac{\text{Perceived probability of threat x Perceived awfulness / costs}}{\text{Perceived ability to cope with danger + Perceived "rescue factors"}}$$

Figure 1 Factors increasing the degree of anxiety (adapted from Salkovskis 1996c)

This model postulates that individuals with anxiety problems evaluate the costs and awfulness of a threat and estimate how likely this threat may be. They also think about their coping abilities and what other actions can be performed to deal with and / or prevent the threat.

Factors that are involved in the maintenance of anxiety are illustrated in the following model by Salkovskis (1996c).

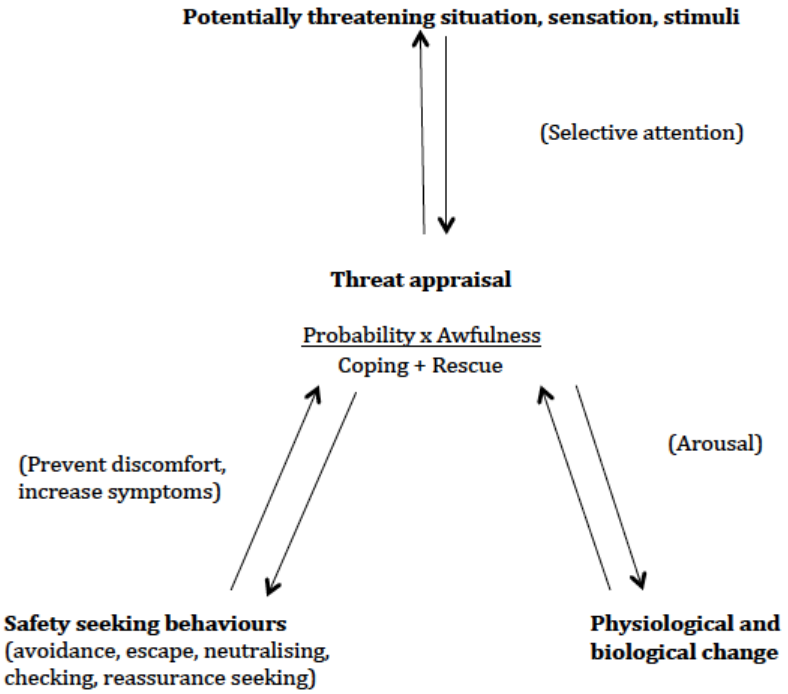


Figure 2 Psychological and physiological factors associated with the maintenance of anxiety (adapted from Salkovskis 1996c)

This model illustrates how patients become more sensitive to information that is congruent with their degree of perceived danger and therefore selectively extract that information and scan their environment for further evidence. Anxiety has direct and indirect physiological effects, which are in turn interpreted as both signs of danger and confirmatory evidence of their fears. This is especially the case if bodily sensations are linked to the nature of anxiety (i.e. in health anxious patients, or patients suffering from panic attacks). A vicious circle can develop in which individuals get trapped and the perception of threat is likely to increase as a result. Lastly, Salkovskis explains that certain

behaviours, performed to compensate for high anxiety or used to prevent harm from happening, increase the preoccupation with threat and are key factors in the maintenance of anxiety symptomatology.

Anxiety in cancer patients

There appears to be a consistently found association between anxiety symptoms and well-being in patients with a cancer diagnosis and who have invasive surgery (Ernstmann et al., 2009; Hasenbring et al., 2011; Hyphantis, Paika, Almyroudi, Kampletsas, & Pavlidis, 2011; Knowles et al., 2013; Ristvedt & Trinkaus, 2009; Sales, Carvalho, McIntyre, Pavlidis, & Hyphantis, 2014; Simon et al., 2005; Tejido-Sanchez et al., 2014).

State and trait anxiety in cancer patients has been examined in various studies. Ernstmann et al. (2009) conducted a cross-sectional study including 710 patients suffering from various cancer diagnoses including colorectal cancer. They found that approximately 20 % of patients were in need of psychosocial support. The results of this study show that women tend to be more affected than men and might therefore required more psychological treatment. The emotional functioning of patients was found to be a central predictor for unmet needs in this sample.

Ristvedt et al. (2009) examined health related quality of life in patients who had survived rectal cancer. They found that a high level of trait anxiety was the strongest predictor for low levels of health related quality of life. Patients who suffered severe faecal incontinence were also more likely to rate their quality of life in regards to their own health as low. Interestingly, the presence of a

colostomy did not appear to be related to the outcome. The authors argue that incontinence may be experienced as uncontrollable and chronically stressful, whereas patients might feel more able to learn to manage their stoma and adapt to it.

A study investigating the impact of genetic counselling for hereditary colorectal cancer found that, in particular, young men with anxiety-related cognitions and a previous cancer history are a particularly vulnerable group (Hasenbring et al., 2011). Misconception and over-evaluation of hereditary cancer risk were found to be the crucial cognitions that were related to anxiety.

Qualitative research showed that patients' emotional functioning initially reflected on their physical condition (i.e. the idiosyncratic symptoms they experienced) rather than the disease as such but as independence of surgical treatment was regained, patients' awareness of their underlying disease intensified and so did the associated anxiety (Worster & Holmes, 2008).

A study investigating adaptation and quality of life in a sample of 114 colorectal cancer patients found that anxiety as well as depression were main predictors for quality of life (Graça P. et al., 2012) In particular patients with recurrent cancer diagnosis showed high levels of anxiety and traumatic stress. Graça et al. also illustrated in their study that patients with high levels of traumatic distress had increased symptoms distress. The association between anxiety and symptoms distress was also found in other studies (Zhang et al., 2014; Zhang et al., 2015). Zhang et al. also described how a nurse-led

intervention for colorectal patients was effective in increasing self-efficacy and overall well-being in patients.

The relevance of health anxious thoughts and behaviours

The studies discussed above describe a relationship between anxiety and illness perception, and struggles with adjustment and low levels of quality of life in patients with physical disability and a cancer diagnosis. However, the particular processes underpinning the association between anxiety and adjustment are not fully understood. Links have been established between mental health problems, in particular anxiety in patients suffering from physical illness, and maladaptive coping and lower levels of adjustment. Yet, it would be a worthwhile investment to analyse those processes leading to less good outcomes for patients by looking at the specific aspects of anxiety that might be related to decreased adjustment and distress.

Health anxious thoughts and behaviours might be of particular relevance in the context of chronic health issues. Patients suffer from a profound level of anxiety in respect of thoughts about their own health or the health of others. They are often characterised by a distorted perception of health threats (i.e. heightened perception of bodily sensation) and may misinterpret normal bodily symptoms as a sign of serious illness. Thus, health anxiety can lead to behaviours that are performed to prevent feared negative predictions. This may decrease symptoms in the short-term, but is likely to maintain health anxiety in the long-term.

In the following section, the cognitive-behavioural model of health anxiety will be discussed in detail and its prevalence in physical health problems, including cancer patients, presented and discussed.

HEALTH ANXIETY

Diagnostic criteria health anxiety

The DSM-IV (American Psychiatric Association, 2013) defined health anxiety according to the following criteria. Recent changes according to DSM-V are described below.

A. Preoccupation with fears of having, or the idea that one has, a serious disease based on the person's misinterpretation of bodily symptoms.

B. The preoccupation persists despite appropriate medical evaluation and reassurance.

C. The belief in Criterion A is not of delusional intensity and is not restricted to a circumscribed concern about appearance.

D. The preoccupation causes clinically significant distress or impairment in social, occupational, or other important areas of functioning.

E. The duration of the disturbance is at least 6 months.

F. The preoccupation is not better accounted for by Generalized Anxiety Disorder, Obsessive-Compulsive Disorder, Panic Disorder, a Major Depressive Episode, Separation Anxiety, or another Somatoform Disorder.

The newly published 5th edition of the DSM replaced the diagnosis of hypochondriasis with illness anxiety disorder or somatic symptom disorder. These changes predominantly reflect on the negative perception of the term 'hypochondriac' and the associated impact it may have on patients and their relationship with health care professionals (American Psychiatric Association, 2013). The authors illustrate that patients with health anxious thoughts and behaviours often indeed exhibit somatic symptoms and that had not been taken into account in the previous versions of the diagnostic criteria for health anxiety in the DSM IV. Patients without somatic symptoms will now receive the diagnoses of illness anxiety disorder should their health anxiety not better be explained by a primary anxiety disorder.

Use of terminology in the thesis

For the purpose of this thesis, the general term 'health anxiety' is used throughout in the interest of simplicity and ease of reading. The new definitions and suggestions for describing health anxious individuals are taken into account. However, it seems pragmatic to use a single term. Moreover, the term hypochondriasis will be used when describing the levels of severity of health anxious symptoms based on the scores obtained with the measures used in this study, which still operate with the old terminology.

Cognitive model of health anxiety

Health anxiety has been described as a series of beliefs that one has in regards to developing and / or having a serious medical condition (Salkovskis, 1996c; Salkovskis & Warwick, 1986; Warwick & Salkovskis, 1989, 1990). These beliefs are based on a misinterpretation of physical symptoms as signs for a

serious illness and from this individuals can develop high levels of anxiety about their health. The role of the appraisal processes in determining a threat or a danger is crucial in the context of health anxiety. An individual might experience a situation or stimulus as personally threating, no matter whether this is objectively justified, and this experienced threat is essential to the emotion of anxiety.

The cognitive model of health anxiety (Salkovskis, 1996c) postulates that bodily sensations and symptoms and medical information tend to be interpreted as more dangerous than they objectively are, and the likelihood of an illness as higher than it probably is. However, the patient may believe that they are unable to prevent the health threat and thus, evaluate their coping abilities as low.

Importantly in the context of the current study, Salkovskis (1996c) outlines that past experience of illness, in self and others, impact on the above processes profoundly. Assumptions about illness are developed through personal and vicarious experiences and are influenced by external sources therefore including how the media presents information. Assumptions and beliefs about health and illness may be a constant source of worry or they might be triggered by specific incidences such as developing (or witnessing) an illness.

As described above, assumptions and beliefs (= anxious cognitions) increase the likelihood that a person selectively extracts information that confirms the belief and delivers them the evidence accordingly. Worry (i.e. “If I worry about it, I can prepare for it.”) has been discussed as a common coping strategy in patients with anxiety disorders (Wells & Carter, 1999, 2001; Wells & Papageorgiou, 1998;

Wells et al., 2010). Salkovskis (1996c) speaks of a *confirmatory bias* and describes how unfamiliar bodily sensations or new information about illness can lead to catastrophic interpretations (i.e. "The pain in my stomach means I have cancer." "My heart is raising; that must mean I am having a panic attack." "I don't feel pregnant. Therefore something must be wrong with my baby.").

The cognitive model of health anxiety (see figure 3), Salkovskis (1996c); (Salkovskis & Warwick, 1986) proposes four factors, directly involved in the maintenance of, and preoccupation with, worries about health.

1. *Increased physical arousal* is interpreted as a sign of illness, which causes more anxiety and subsequently increased physical symptoms. This vicious circle is hypothesised to be associated with the before mentioned confirmatory bias.
2. *Selective attention* in the context of health anxiety is related to normal bodily sensations and symptoms being perceived as novel and patients perceive the diversion from normal as pathological and threatening. This, in turn, can cause anxiety and the associated autonomic arousal may also be interpreted as a sign of ill health.
3. *Safety seeking behaviours* are common in health anxious patients and are performed to counteract the intensely experienced feelings of anxiety. As described above, patients worry about internal stimuli, but those internal cues can be triggered by external factors such as hearing or reading about an illness. Patients may use various forms of reassurance (i.e. talking to partner, family members, close others,

medical professions, researching sources of information, accessing health care agencies, checking body for signs of illness). Avoidance is another safety seeking behaviour and can be found in health anxious patients often in the form of avoiding strenuous exercise, avoiding health information, and using medication. Safety seeking behaviours are reinforced by the short-term reduction of anxiety, but this is at the expense of increasing the preoccupation with health and illness and thus, the associated worry and anxiety in the long-term. These behaviours also prevent the habituation to anxiety provoking stimuli and can therefore lead to persistent distress and maladjustment.

4. *Beliefs and misinterpretations of symptoms and the impact on medical communication* are one of the most crucial elements of health anxiety. The aforementioned confirmatory bias for health related information is important to consider when communicating with patients, who are likely to misinterpret information given in consultations.

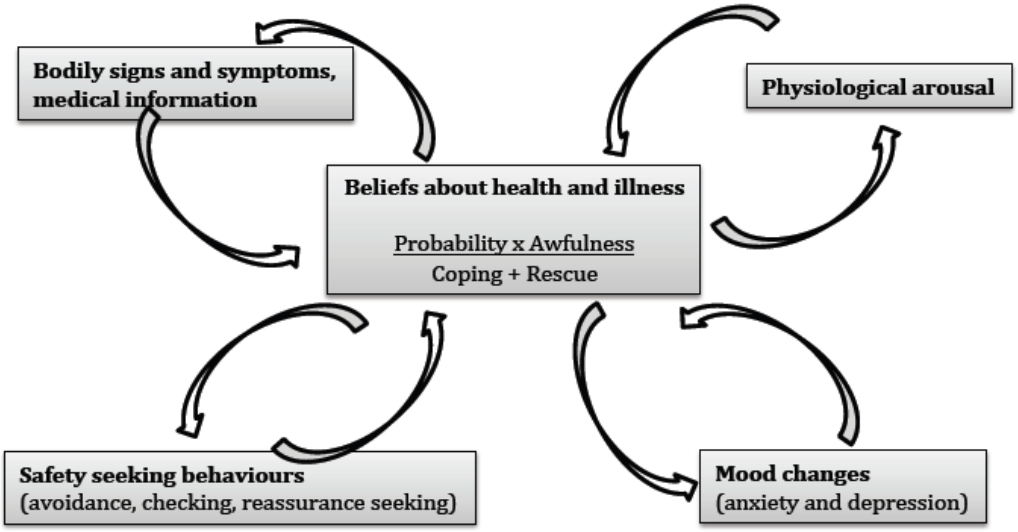


Figure 3 Factors maintaining threat beliefs in health anxiety (adapted from Salkovskis 1996)

Treatment of health anxiety

The more extreme form of health anxiety – hypochondriasis – was thought to be untreatable (Rachman, 1998) but cognitive models of health anxiety now suggest options for helping patients to overcome this anxiety related to health and illness (Clark et al., 1998; Salkovskis, 1996c).

Cognitive behavioural treatment focuses on reaching a shared understanding of the problem, which is followed by a variety of strategies (Salkovskis, 1996c). As explained above, one of the main aims of therapy is to help patients to understand that their safety seeking behaviours are prolonging their suffering by fuelling the vicious circle of anxiety symptoms and the behaviours performed to

diminish those symptoms. Patients are familiarised with techniques, such as diarising their health anxious cognitions, and their emotional and behavioural responses. Behavioural experiments are used to tests those feared predictions and intended to help the patient come to the conclusion that their worst-case scenario does not occur. Health anxious patients may need time before they feel ready to engage in the behavioural work. Discussion techniques to challenge patients' appraisal, assumptions, and core beliefs are important to enable long-term therapeutic gain for the patients.

Health anxiety in chronic health conditions

Health anxiety is predominantly studied in non-medical samples, although research has shown that is it prevalent in patient groups with medical conditions (Alberts, Sharpe, Kehler, & Hadjistavropoulos, 2011).

Prevalence rates for health anxiety in various patient populations groups are high, ranging from 24.7 % in neurology patients, followed by respiratory patients (20.9%), gastroenterology (19.5%, cardiology (19.1%), and endocrinology (17.5%) (Tyrer et al., 2011). This data was derived from a large cohort sample (N = 28,991) attending health care settings in the UK. Almost 20% overall (N = 5,747) were diagnosed with clinical health anxiety using the Short Health Anxiety Inventory (Salkovskis, Rimes, Warwick, & Clark, 2002).

The authors discuss that health anxiety in patients suffering from a medical condition might be linked to greater morbidity and could also lead to increased health care costs. Those patients with a complex presentation of medical problems, in combination with health anxious behaviours and thoughts, might

present more often in primary and secondary care settings and seek reassurance from medical staff, who might respond by offering more investigations and examinations. This, inadvertently, reinforces symptomatology in patients (Tyrer et al., 2011).

The above research group also conducted costs analysis with the intention of finding out which factors predict higher costs in health care settings (Barrett et al., 2012). They found that increased health care costs are associated (tested with multiple linear regression) with poorer social functioning, lower health related quality of life, and lower levels of generalised anxiety. These results suggest that socially poorly functioning individuals may access services more often to receive care. Equally, poor health related quality of life may be related to more severe symptoms and therefore be related to increased costs. An interesting finding, however, is that the authors found a negative association between generalised anxiety and costs, suggesting that patients who feel generally anxious avoid services. They did not find a significant association between health anxiety and costs. This study has helped to make more sense of patient behaviour and how this may relate to service use and costs by showing that particularly anxious patients had lower health care costs.

A recent study has investigated health anxiety in chronic pain (Rode, Salkovskis, Dowd, & Hanna, 2006). Rode and her colleagues found that health anxiety was significantly higher in individuals suffering from the condition compared to healthy controls. They used the short version of the Health Anxiety Inventory (Salkovskis et al., 2002) as a diagnostic estimate and concluded that

36.7 % were suffering from hypochondriasis (the severe form of health anxiety; using a cut-off point of 18 on the scale) and 51.1 % scored above a cut-off point of 15 suggesting that they presented with health anxiety. In this study, patients with higher levels of health anxiety reported more pain and women tend to report more pain than men; neither age nor gender was correlated in the extent that health anxiety was exhibited by this sample (Rode et al., 2006).

The model of health anxiety (Salkovskis, 1996c) suggests a reciprocal relationship between health anxiety and increased physical symptoms, and, indeed, the authors found a significant correlation between health anxiety and more intense pain (Rode et al., 2006). Increased use of safety seeking behaviours in pain patients, who report to be health anxious, was found in other research (Tang et al., 2007). A more recent study (Hayter and Salkovskis, personal communication) demonstrated that high health anxiety is associated with lower quality of life in people with Multiple Sclerosis. Furthermore, the research group's (Salkovskis, personal communication) preliminary findings suggest that interventions that target health anxiety have a positive impact on quality of life. This suggests that health anxious thoughts may play a causal role in quality of life and adjustment to chronic illness.

A study investigating health anxiety in patients with type 1 or 2 diabetes (N = 414) showed that 24.1% of patients had elevated levels (Janzen Claude, Hadjistavropoulos, & Friesen, 2014). Health anxiety was more prevalent for younger people and those who had been recently diagnosed. Moreover, health anxiety was related to trait anxiety and poorer adherence to treatment / life-

style regime. Lower levels of health anxiety appeared to be related to higher quality of life.

Research in Multiple Sclerosis (MS) suggest that, similar to other research, about a quarter of patients suffer from clinical levels of health anxiety (Kehler & Hadjistavropoulos, 2009). The authors also investigated coping and found that patients with health anxiety and generalised anxiety used emotional-preoccupation coping, whereas only health anxiety was uniquely related to problem-focussed coping.

Health anxiety in cancer patients has been examined in respect of cancer screening. A positive association between health anxiety and cancer detection was found for men (although not for women) suggesting that health anxiety may motivate self-examination and therefore lead to early detection (Knudsen, Berge, Skogen, Veddegjærde, & Wilhelmsen). Neither levels of distress caused by health anxiety were accounted for in this study nor were safety seeking behaviours investigated. It could have been an advantage to do so as well as to compare the genders.

Other research has also found links between health anxiety and cancer screening. Miles (2006) followed up patients undergoing colorectal cancer screening. Health anxiety and other psychological variables were assessed before and after screening. They found that health anxious patients were both more anxious and worried about colorectal cancer before the screening procedure. However, highly health anxious patients, in comparison to low health anxious patients, experienced a greater reduction in anxiety and worry following the

consultation. These results should be considered with caution as the cognitive model of health anxiety describes how reassurance seeking may be associated with short-term anxiety reduction, but long-term maintenance of symptoms (Clark et al., 1998).

In other studies including cancer patients, links have been found between health anxiety and symptoms severity (Leonhart et al., 2015) although much of the research in this patient group has predominantly investigated associations between anxiety in a more general sense and various outcomes such as health related quality of life (Escobar et al., 2013; Hassel et al., 2012; Jörngården, Mattsson, & von Essen, 2007; Park, Kim, Jiang, & Lawson, 2014; Spiegel, Gerharz, Müller, Riedmiller, & Faller, 2011; van Esch, de Vries, van der Steeg, & Roukema, 2008).

In summary, research indicates that health anxiety specifically can be an important factor to consider in medical conditions. Estimates for prevalence rates of health anxiety amongst medically ill patients are high and research has shown that health anxious thoughts and feelings and the often associated maladaptive coping efforts in the form of safety seeking behaviours, can complicate treatment and lead to increased health care costs.

Patients undergoing stoma surgery, which in many cases might have been preceded by a serious or life-threatening illness such as colorectal cancer, might suffer from anxiety, yet the role of health anxiety in this sample has not been explored to date.

THE IMPORTANCE OF SELF-EFFICACY IN HEALTH CONDITIONS

The previous section has outlined that there is research suggesting stoma surgery is associated with maladjustment and emotional suffering. Health anxious thoughts and the associated safety seeking behaviours might play a particular role within the adjustment processes of this patient group, which will be examined in this thesis.

However, it should also be noted that many patients adjust well to a life with a stoma. Much attention is often paid to those factors that may lead to a decline in well-being and a decreased quality of life such as outlined above. Taking such a stance is likely to lead to a lack of understanding of those determinants that are protective and should be targeted in clinical interventions in order to increase the skills set and coping abilities of patients with illness.

Thus, a crucial concept in respect of coping with chronic illness and invasive operations, such as stoma surgery, is self-efficacy. This has been defined as the individuals' evaluation of having the skills and abilities to cope with a situation or event and to successfully execute behaviours required to produce a certain outcome (Bandura, 1977, 1982, 1989, 1997).

Bandura (1977) distinguishes between 'outcome' and 'efficacy expectations'. Outcome expectancies refer to a person's belief that behaviour will lead to an expected outcome, whereas efficacy expectancies relate to a person's belief in being able to perform the actions necessary for the outcome to happen. Low self-efficacy has been related to stress and depression (Bandura, Pastorelli, Barbaranelli, & Caprara, 1999; Merluzzi, Philip, Vachon, & Heitzmann, 2011) and

might be associated with maladaptive coping (Bandura, 1982; Bandura, Caprara, Barbaranelli, Gerbino, & Pastorelli, 2003).

The processes underlying the relationship between self-efficacy and distress are complex. Bandura (2003) suggests that perceived self-efficacy plays a pivotal role in emotion regulation and these processes can be associated with not only positive and negative affects but also impact on cognitive, motivational, and decisional factors. Bandura further explains that this proposed regulation of individual coping efforts operates indirectly through the initiation of behaviours such as coping or seeking social support, and is dependent on which self-regulative actions a person adopts. Self-efficacy beliefs can influence whether a person thinks constructively or destructively, how much effort there is invested in considering coping and problem solving options, whether a person perseveres against the background of challenges, how resilient or vulnerable someone is in respect of depression and stress, and also what types of decisional processes someone engages in (Bandura et al., 2003). Thus, it can be concluded that individuals with high levels of self-efficacy might be more likely to engage in behaviours that help to regulate negative affect.

Self-efficacy is indeed in a crucial concept to consider in stoma management and care, as it is a highly overarching concept of coping, to be used in all aspects of human behaviours in situations that require the individual to resort to coping strategies. In the context of health care, self-efficacy needs to be paid particular attention because it is a targetable and modifiable variable in interventions for people with health and / or mental health difficulties.

Self-efficacy in stoma patients

In the context of stoma management, Bekkers et al. (Bekkers, van Knippenberg, van den Borne, & van Berge Henegouwen, 1996; Bekkers, Vandenborne, Bergsma, Poen, & Vanbergehenegouwen, 1993) outline that stoma patients are faced with at least two major challenges and even threats. On the one hand, these patients are required to cope with a potentially life threatening illness and, on the other hand, they have to find ways to live with the consequences of having a stoma. These cumulative factors might lead to a high demand of coping resources in this patient group and the authors found that psychosocial adjustment is influenced by self-efficacy expectations (Bekkers et al., 1996). They concluded from their results that the more a patient feels competent to function after surgery, the fewer the psychosocial difficulties experienced post-operatively.

A study (Simmons et al., 2007) examined stoma acceptance, stoma care self-efficacy, and inter-personal relationships as predictors for psychological adjustment. They collected data from 51 patients with colostomies 6 months after surgery and found that stoma care self-efficacy was the strongest predictor for adjustment explaining almost 60% of the variance in the outcome. The results of this study highlight the importance of enhancing self-efficacy in patients to prevent psychological distress and maladjustment. However, as past research has shown, a previous psychiatric history can influence how patients adjust to their stoma (Thomas et al., 1987a, 1987c; White, 1998; White & Unwin, 1998), although the cross-sectional design of this study may limit the conclusion that can be drawn from the results. The authors collected data 6 months post-surgery

and argue that adjustment will have reached a plateau by this time. Mental health status at the time of surgery or a past psychiatric history was not assessed, which is a shortcoming. Moreover, effects of time on the outcome were not accounted for by using this design. It would also have been worth investigating the sources that helped increase self-efficacy in patients. As described above, stoma care and nursing has been found to be beneficial in fostering stoma care self-efficacy and coping (Metcalf, 1999; Thomas et al., 1987a, 1987c; Thomas et al., 1988; Worster & Holmes, 2008; Zhang et al., 2014; Zhang et al., 2015; Zheng et al., 2013).

AIMS AND HYPOTHESES OF THE CURRENT STUDY

The research reviewed above shows that patients undergoing stoma surgery are faced with multifaceted challenges and difficulties both physical and psychological. From previous research, it appears that most patients exhibit some negative affect shortly after the surgery. However, many patients adjust well to their stoma. For a percentage of patients, coping with the stoma is difficult and this seems to be particularly the case if there are mental health problems such as anxiety and depression. Adjustment is an on-going and complex process that may vary over time. The research cited here gives strong evidence that adjustment and health related quality of life are linked to psychiatric presentations in patients. Anxiety especially has been related to increased morbidity or exacerbated physical symptoms and struggles with adjustment.

Health anxiety appears to play a particular role in physical health conditions and has been found to be highly prevalent in this population. This may increase

distress and disability and is therefore an important clinical point to consider in health care settings. Research demonstrating that health anxiety is associated with adjustment in stoma may suggest that psychological interventions focussing on health anxious thoughts and behaviours could potentially be beneficial in helping patients to manage their symptoms and to adjust.

Health anxiety in the context of stoma surgery might be of particular interest. Stoma surgery is often performed as a lifesaving procedure and as part of the surgical treatment for colorectal cancer and other physical problems. Thus, part of the adjustment process post-surgery is to come to terms with the diagnosis and prognosis. Patients therefore have to process a considerable amount of medical information and learn new skills to manage their stoma. Clinical levels of health anxiety are likely to impact on these processes of adjustment.

The review of the literature also showed that the way patients are prepared for the stoma before their operation impacts on how they deal with it afterwards. Thus, stoma nurses and their involvement in pre-operative counselling seems to play an important part in adjustment in patients by enhancing stoma self-efficacy which, in turn, appears to be a strong predictor for the coping ability of patients, who might benefit from adequate support prior surgery.

Research questions and hypotheses

Based on these considerations, and the body of research evidence reviewed, the main aim of this study was to investigate the frequency of health anxiety in a sample of patients undergoing surgery that results in a stoma. Further, the aim of this project was to investigate the *relationship between psychological adjustment*

in patients undergoing stoma surgery and several predictors. Primarily, it was of interest to find out whether indications of health anxious thoughts and behaviours can distinguish between patients adapting well to living with a stoma from those who are struggling to adjust. Difficulties with adjustment are defined as a psychological response to demands and stresses, in which individuals exhibit negative affects. The study aimed to provide clinical implication such as describing factors that are likely to increase the risk of maladjustment after surgery and to discuss implications for health care providers in delivering interventions for this patient group.

The main aim of this study was to investigate health anxiety in a population of stoma patients and to test the *association between health anxiety, stoma care self-efficacy, and psychological adjustment to stoma after surgery in a cross-sectional sample*. This model was chosen based on previous research that has shown an association between self-efficacy and adjustment. Health anxiety was added a novel factor.

We tested the ***hypothesis*** that lower levels of stoma adjustment are associated with higher levels of health anxiety and lower levels of stoma care self-efficacy. The above described model was further explored by adding the following variables (i) satisfaction with pre-operative preparation by clinical team, (ii) severity of pre-operative physical symptoms, and (iii) time since surgery. We wanted to find out whether by controlling for these potentially influential variables, health anxiety and self-efficacy remain significant predictors for adjustment.

A second aim was to find out whether the relationship between stoma care self-efficacy and the levels of psychological adjustment in patients are mediated by their health anxious thoughts and feelings. Thus, the ***hypothesis*** was tested that health anxiety acts as a mediator for the relationship between self-efficacy and adjustment.

The third and last aim was to investigate whether *patients undergoing emergency stoma surgery differ from patients undergoing planned surgery*. We tested the ***hypotheses*** that emergency patients feel less prepared for the surgery, have higher levels of health anxiety, lower levels of stoma care self-efficacy, lower levels of stoma adjustment, and higher levels of overall distress in comparison to patients who underwent planned surgery.

Initially, it was hoped to collect data to investigate theses hypotheses in a longitudinal sample. We intended to test the hypothesis whether *pre-surgery health anxious thoughts and behaviours, stoma care self-efficacy, and stoma related variables* such as satisfaction with pre-operative preparation, and levels of seriousness of pre-surgery symptoms *predict post-surgery adjustment to stoma*. Several reasons might have led to the failure to recruit sufficient longitudinal data to tests the hypotheses in a pre-post design. Those reasons and the resulting limitations for this study are discussed later (please see below). Consequently, a pragmatic approach was applied and the study used a cross-sectional design.

CHAPTER 2: METHOD

This chapter describes the methods used in the study and the procedures applied to investigate the research questions raised in the context of psychological adjustment in patients undergoing stoma surgery. This study had a cross-sectional design using regression and mediation analyses and group comparative statistical methods. Fifty-eight patients, who had either planned or emergency surgery, were recruited via websites, social media, or face-to-face by stoma care nurses and the researcher. The researcher obtained informed consent and participants completed a set of reliable and valid self-report measures either with the researcher as a structure interview or alone. All study materials are added to the appendix (see below).

ETHICAL APPROVAL

Ethical approval for the study was obtained from the National Research Ethics Service (REC reference 14/NW/1286, IRAS project ID 124924) in December 2014 after minor amendments. The study protocol was also submitted for ethical approval to the Royal Holloway, University of London ethics committee and approved. St. Peter's and Ashford Hospital Chertsey Research and Development Department granted site-specific ethical approval.

PARTICIPANTS

Sample

Once ethical approval was obtained, the recruitment phase of this cross-sectional sample lasted 3 months and took place from January 2015 until March 2015. A total of 192 patients were approached within a NHS setting and a further

23 participants were recruited from internet-based sources. A subsequent sample of N = 58 participants was recruited for this study; 31 patients were male and 27 female. The average age in this sample was 64.09 (SD = 14.63). A fairly equal number had either emergency (N = 26) or planned (N = 32) surgery.

Recruitment

The hospital site used for the recruitment of this study was St. Peters and Ashford Hospital in Chertsey, where stoma care nurses supported the acquisition of participants. The below described procedure of recruitment was initially hoped to be used for recruiting patients for a longitudinal sample. During the 3 months of recruitment, a total of N = 25 were approached by the nursing team and subsequently N = 5 were included in the study through this arm of recruitment. The reasons for the exclusion of participants varied. Some patients had changed their mind and expressed that they did not feel able to participate at the current time due to their health status or simply because they did not want to complete the questionnaire. Other patients had not received a stoma in their operation or it was shortly (i.e. within 6 weeks) reversed, which was neither known nor expected pre-surgery. It was decided that a period of at least 6 weeks of living with a stoma was necessary to be eligible for taking part in the study.

In order to recruit participants, the nursing team made first contact with potential participants and talked to patients about the study during the pre-surgery preparation appointment. If patients were interested to learn more about the study, they were asked to complete a contact form that was given to the researcher, who then sent out the study materials (information sheet,

consent form, and questionnaire). The patient was phoned shortly after the contact form was received and given the opportunity to ask questions about the research. It was not possible to reach patients before their surgery as the pre-operative meeting with the stoma nurse usually took place very close to the operation date. By the time the researcher had received contact details, the patients had typically had their surgery.

Once informed consent was obtained the assessment took place as a structured interview at a mutually convenient time or was completed by the patients on their own, in both cases at least 6 weeks after their surgery. The researcher informed the participant that questions are asked in a structured manner without having the possibility to change the wording or content.

In addition to the recruitment of patients by the stoma nurses, all patients who had stoma surgery in the past 12 months at St. Peters Hospital (January 2014 – December 2014) were approached. A letter was sent to these patients alongside the information sheet, consent form, and the questionnaire. Patients were encouraged to complete the consent form and provide contact details. They were offered to complete the questionnaire in their own time or with the researcher on the phone. A total of 167 patients were approached and 42 responded and completed the assessment.

Social media and support groups that act online were another arm of recruitment for this study. Press offices and website administrative staff were contacted and advertised the study to users. Organisations agreeing to help for recruitment purposes included Beating Bowel Cancer and The Colostomy

Association. The advert that was distributed to those organisations and websites is added to the appendix. Potential participants contacted the researcher by email and were sent the information sheet and the questionnaire. Participants were given the choice to either complete the questionnaire in their own time or as a structured interview with the researcher on the phone.

Figure 4 outlines the sample size and the three recruitment arms. In summary, patients were approached and recruited either retrospectively or prospectively.

- The stoma care team at St. Peter's Hospital offered the participation in the current study to each patient, who had his or her surgery between January 2015 and March 2015 (prospective sample).
- Patients who had their surgery between January 2014 and December 2014 (retrospective sample). This sample was recruited from St. Peter's Hospital and support organisations.
- Patients who had their surgery between January 2014 and December 2014 (retrospective sample) were recruited from social media and support groups.

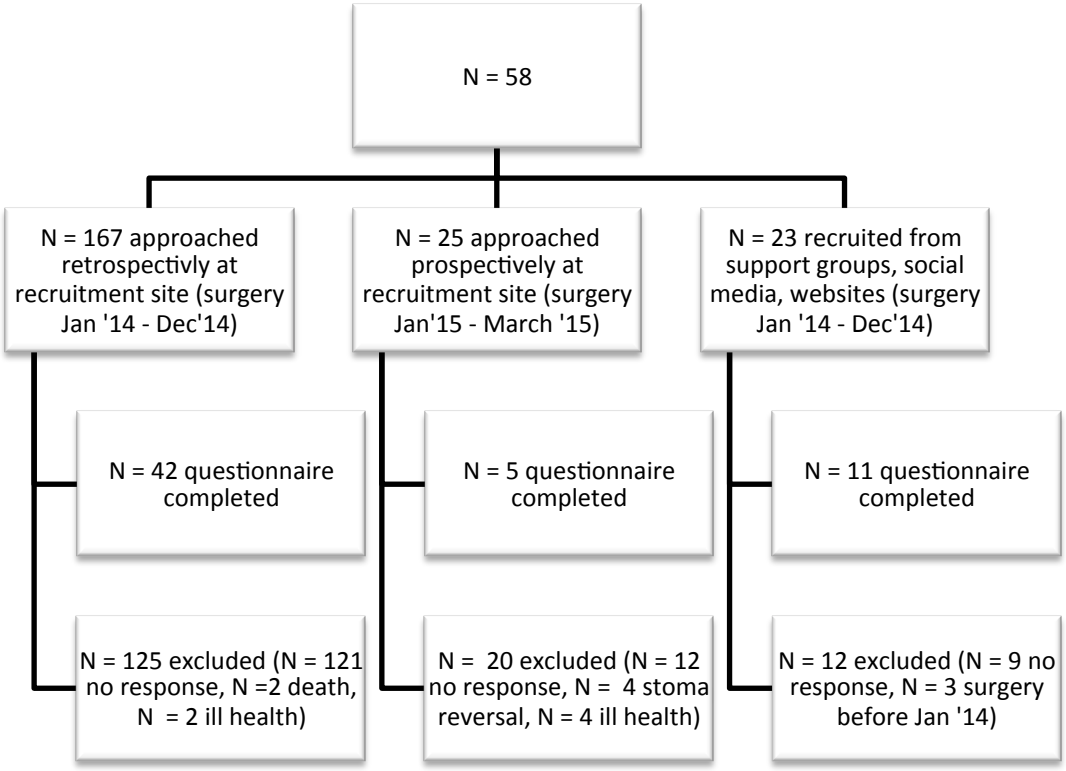


Figure 4: Sample flow chart

As shown in Figure 4, 215 patients, who have had stoma surgery were approached, yet only 27% agreed to participate and/or were eligible to take part in this study. This relatively low rate of recruitment illustrates the difficulties that might arise in recruiting this patient group, especially for a longitudinal study. This will be discussed later in more detail.

Inclusion and exclusion criteria

Participants were eligible to take part if they: had surgery that resulted in a stoma within the past 12 months, have had their stoma for at least 6 weeks, had capacity to decide whether they would like to take part, had sufficient English language skills, and were not known to suffer from a psychiatric disorder that

could impact on the assessment or the assessment could negatively influence their well-being. In the cases where the stoma was reversed shortly after surgery (i.e. within 6 weeks), participants were excluded from the assessment. This was discussed with patients and met with agreement as they also felt that their experience of living with a stoma was limited and thus, would make it difficult to give a comprehensive account in the assessment. Exclusion criteria also included no return of assessment measure and declining to take part.

ASSESSMENT MEASURES

All questionnaires used in this study are added to the appendix.

Clinical data

Hospital Anxiety And Stress Scale (HADS-A and HADS-D; Zigmond & Snaith, 1983): A 14-item self-report measure assessing general levels of anxiety and depression over the previous 7 days. Scores are calculated on a 4-point Likert scale and summed to obtain the total score. The authors propose a suggestive threshold for elevated levels on both subscales at a score of 8. The clinical threshold for the scales is suggested at a score of 11.

Dependent variable

Ostonomy Adjustment Inventory (OAI-23; Simmons, Smith, & Maekawa, 2009) is a 23-item self-report measure assessing psychosocial adjustment in stoma patients on four factors: 1) acceptance – coming into terms with the stoma, 2) pre-occupation with stoma, 3) social engagement, and 4) anger expression. The questionnaire has high levels of reliability (Cronbach's alpha = .93, split-half reliability = .91, test-retest reliability = .83) and has been shown to

be a valid measure (r = .72 with Felton's Acceptance of Illness Scale). The measure is a specific, practically relevant inventory for adjustment in a population of stoma patients. The OAI-23 has been used and validated in many cultural contexts (Santos et al., 2011; Simmons, Maekawa, & Smith, 2011).

Proposed predictors

The short version of the ***Health Anxiety Inventory*** (SHAI; Salkovskis, Rimes, Warwick, & Clark, 2002) is an 18-item measure of clinical and non-clinical health anxiety. The first 14 items measures symptoms and criteria of health anxiety, whereas the next 4 items measures the 'awfulness' in terms of costs of a particular illness from the standpoint of the participant. Participants were instructed to think about future potential illnesses. The inventory has good internal consistency (Cronbach's alpha = .89). The authors propose that the SHAI is sensitive across a range of levels of health anxiety (mild levels to hypochondriasis) and it should distinguish between patients suffering from health anxiety and those with an actual physical illness but who are not excessively concerned about their health.

Research has tested whether the patients with and without medical problems respond differently to the SHAI and found that the measure can be used in medical contexts without the fear of significant bias (LeBouthillier, Thibodeau, Alberts, Hadjistavropoulos, & Asmundson, 2015).

Stoma Care Self-Efficacy Scale (SCSES; Bekkers, et al., 1996) is a self-report measure assessing two components of stoma related self-efficacy: stoma care self-efficacy (13 items, Cronbach's alpha = .94) and social self-efficacy (9 items,

Cronbach's alpha = .95). The two scales are highly correlated (r = .73), which, if used in the same analysis, can lead to unstable regression coefficients (Field, 2009; Graziano & Raulin, 2003). Bekkers (1996) has suggested the use the subscales separately and not in the same analysis.

Additional predictors for explorative analysis

Satisfaction With Pre-Op Preparation: six items, 10-point Likert scale, higher scores indicate higher satisfaction, one overall score; adapted from previous use by Salkovskis et al. 2004 and Wroe at al. 2003 (Salkovskis, Wroe, & Rees, 2004; Wroe & Thomas, 2003)

- Item 1: "How much do you feel that you were involved in the decision around having surgery that result in a stoma?"
- Item 2: "How much information do you feel you have been given about why you need to have a stoma?"
- Item 3: "How much information do you feel you have been given about how to look after your stoma?"
- Item 4: "How well do you feel prepared for the negative aspects (physical) of having a stoma based on the information you received?"
- Item 5: "How well do you feel prepared for the negative aspects (psychological) of having a stoma based on the information you received?"
- Items 6: "Do you feel you received overall the appropriate amount of information of how to live with a stoma?"

Seriousness of preoperative physical symptoms (one items, 10-point Likert scale): "How burdensome have you experienced your physical symptoms prior to your stoma surgery?"

Time since surgery: 1 item, measured in weeks

DESIGN AND PROCEDURE

This study had a cross-sectional design. Once informed consent was obtained, participants either completed a set of valid and reliable questionnaires with the researcher as a structured interview or on their own.

The completion of the questionnaire was piloted with two individuals (lay people, neither belonging to a patient group nor a clinical professional) and it took the person who completed it as a structured interview 45 minutes. The person who completed it as self-report measures took 30 minutes for completion.

All assessments with participants from the prospective sample and those recruited from internet-based sources completed the questionnaire as a structured interview. For many, it took 1 – 2 hours to complete the assessment. This was mainly due to conversations about life circumstances and the illness history. Participants responded positively to the necessity to be thoroughly structured in the interview and adhered to this procedure. The sample that was recruited from the mail out to patients, who had surgery in the past 12 months at St. Peters Hospital, all completed the questionnaire on their own with the exception of 3 patients who opted for a structured interview.

Each questionnaire outlined a specific set of instructions; for example the timeframe that should be considered when answering the questions and that questions should be answered without 'over-thinking' the response. The rating scales were explained as were how the numbers related to a specific response.

After the completion of the questionnaire, participants were debriefed and offered to receive a summary of the results of the study. Particularly with those participants that were interviewed, conversations about their mental well-being were inevitable and were often brought up by the patient.

Two participants, recruited from internet-based source, were signposted to services (i.e. General Practitioner, Adult Mental Health Services) that may be able to offer support. Patients from St. Peters Hospital were reminded to discuss concerns and mental health problems with their stoma nurse, who can help to access services that might be able to offer support.

Thus, the needs of the patients, who took place in this study, were considered with much care and the following measures were put into place to respond appropriately to patients who appeared to exhibit distress that may need to be formally assessed and treated.

ETHICAL CONSIDERATIONS

Patients were recruited in a stressful period in their lives and it was considered important to sensitively approach individuals in the recruitment phase as well as to consider the impact the assessment might have on the participant. Therefore, a member of staff at the recruitment site first approached

patients. This was usually the stoma nurse, who met with patients shortly before their surgery. Participants were given the choice to complete the questionnaire alone or with the researcher and author of this thesis on the phone. This approach was chosen to be able to respond appropriately to participants who experience distress when thinking and talking about their experience.

Answering questions about personal feelings and thoughts can be distressing and the researcher responded to participants appearing upset and worried by clarifying whether the assessment should be continued at a different time. For those patients recruited from the hospital site, should the assessment result in patients being identified with significant mental health problems or should a patient appear at risk to self and/or others, the researcher intended to consult the clinical team and liaise with the academic supervisor Dr. Abigail Wroe, who works as a Clinical Psychologist in the stoma service of the recruitment site. Dr. Wroe would be able to offer sessions to participants who may be identified as particularly distressed, or struggling with adjustment. The participant would have been asked for his/her consent to communicate with the stoma care team. No such scenario occurred during the study.

The researcher also encouraged the participant to contact members of his or her care team and to consider options for psychosocial support if indicated. For example, participants were informed about how to access support by contacting the GP or making a self-referral to adult mental health teams. Contact numbers of the latter service were provided if the participant expressed the wish to receive this information.

The information sheet was designed to give the participant a clear understanding of the aims and the procedures, of the study and informed the participant about the study's general purpose, confidentiality, anonymity of data, assessment procedure, withdrawal from the study, and intended dissemination of the results. As part of good practice for obtaining informed consent, the researcher summarised the main points when talking to the participant on the phone and ensured that the participants had understood all relevant information in regards to the study.

The nursing and administration team of the recruitment site supported the acquisition of participants. In order to minimise interruption of the work of the care team, the researcher met the clinical team and discussed and implemented the most effective and least disruptive way of recruiting participants for the study.

SERVICE USER INVOLVEMENT

A service user, recruited from the internet, was asked for feedback on the completion of the questionnaire and his opinion gave valuable insight into the sensitive nature of the assessment and how to deal with challenging situations. All participants were debriefed and offered the opportunity to be informed about the results of the study.

STATISTICAL ANALYSES

All data were analysed using the Statistical Package for the Social Science version 21 (SPSS, Inc., Chicago, IL, & USA).

Power analysis

Based on power analysis and suggested sample sizes for regression analysis (Clark-Carter, 2010), approximately 60 participants were needed for the proposed regression model in this study, which used an alpha level of .05, had 2 independent variables (health anxiety and stoma care self-efficacy) in the main analysis, and sought to achieve a power of .8. These estimates were based on a moderate effect size (r^2 =.13 - .15) that was assumed for the predictor variables. Health anxiety has not yet been investigated in the context of stoma surgery and the post-operative adjustment. Therefore, it was not possible to base the power analysis and its consideration on previous research. We assumed that a moderate effect size seemed appropriate and may help to avoid over-evaluation of the impact health anxiety might have on adjustment. Stoma self-efficacy however, seems to be strongly linked with adjustment and has been found to explain 77% of the variance in this variable in a previous study (Simmons et al., 2007). It is more likely to have a large effect size (which was not reported in the above mentioned study) and therefore, the current study may have needed slightly less participants than the initial power analysis indicated.

We were also interested in finding out how satisfaction with pre-operative preparation by the clinical team, severity of pre-operative physical symptoms, and time since surgery relate to psychological adjustment. This part of the analysis was rather exploratory and we used a commonly described 'rule of

thumb' of 10 participants per predictor plus five for the overall analysis (Clark-Carter, 2010). This meant, including health anxiety and stoma self-efficacy, these further three predictors indicated that an estimated sample size of 55 was needed for a regression analysis with 5 predictor variables but no estimated effect size for these variables. The limitations of this approach are discussed later.

Group comparison

The assumptions for using parametric statistical procedures where tested for each analysis by scrutinizing the skewness and kurtosis (see below). Furthermore, the Levene Statistic, which tests the equality of variance in both groups, using this analysis, was evaluated. A significant test result would indicate a violation of this assumption. If the group comparison had a non-significant Levene Statistic, independent t-tests were used to examine potential differences between the planned surgery and emergency surgery patient group. In case the Levene statistic was significant, non-parametric tests were used. Effect sizes for group differences were calculated when appropriate by using Cohen's d for continuous data.

Regression analysis

Linear regression models were applied to investigate the associations between the above-mentioned variables. Prior to the main analysis, data were also scanned for outliers that could potentially skew the distribution. This was particularly important for the regression analysis. Cook's distances were used to identify potential influential cases. A Cook's distance of 1 is suggested to be

problematic and the model should be tested without these cases (Clark-Carter, 2010; Field, 2009). No case had to be removed from the analysis. Multicollinearity poses a problem for multiple regressions and exists when 2 or more predictors are highly correlated (Field, 2009). SPSS provides a collinearity statistic and it is suggest that a VIF value of greater than 10 and a tolerance level smaller than 0.1 indicate a problem of multicollinearity in the predictor variable.

Mediation analysis

As outlined above, in addition to the main hypothesis, which tested the association between health anxiety, stoma care self-efficacy, and psychological adjustment in stoma patients, the hypothesis of whether health anxiety is a mediator for the relationship between stoma care self-efficacy and psychological adjustment was explored.

A mediator is a variable that can help to establish explanations for the 'how' or 'why' one variable may predict another (Frazier, Tix, & Barron, 2004). Baron and Kenny (1986) first outlined ways of testing variables as mediators for the relationship with a predictor variable and an outcome. Three regression models need to be conducted:

- *Pathway a*: Independent variable as predictor for the mediator variable, whereby the independent variable must affect the mediator.
- *Pathway b*: Mediator as predictor for outcome variable, whereby the mediator must affect the outcome.
- *Pathway c*: Predictor variable and mediator as predictors for outcome variable. The predictor variable must affect the outcome variable;

however, the effect of the predictor variables on the outcome variable must be less than the effect of the mediator on the outcome variable.

- Perfect mediation is given if the predictor variable has no effect on the outcome variable when the mediator is statistically controlled for in the model (*pathway c'*). Partial mediation is given when the relationship between predictor and outcome is significantly smaller and when the mediator is added to the model but the overall model remains significant.

Thus, a mediator variable may help to understand the process through which a predictor influences an outcome (Preacher & Hayes, 2008). In more recent times, the Baron and Kenny method has been criticised for numerous reasons. Preacher et al. (2008) discusses that when using the above described method, there is a danger of conducting a Type I. For example, it is possible to observe a change from a significant pathway c to a non-significant pathway c' and falsely assuming that full mediation is found. However, a potential Type I error may be missed. Preacher et al. further debate that it is also possible that the coefficient for pathway a and b are non-significant because of low statistical power, which can be the case in small sample. Thus, the researcher may assume that there is no effect, yet may have not considered the occurrence of the Type II error.

In order to address the limitations of using linear regression models to test mediation, 'bootstrapping' is now a commonly used statistical procedure to test for mediation in a proposed model. Whereas other methods testing indirect effects assume the normal distribution of data within the sample when

calculating the *p*-value, bootstrapping does not assume the normality of sampling distribution. Moreover, bootstrapping repeatedly samples from the dataset and the indirect effect is estimated with each resampled set of data. Thus, bootstrapping is able to produce a bias-corrected confidence interval for the indirect effect (Preacher & Hayes, 2008).

CHAPTER 3: RESULTS

To reiterate, the study tested the association between psychological adjustment in patients undergoing stoma surgery and several predictors, including health anxiety as the main predictor variable of interest, alongside stoma care self-efficacy and other stoma related variables, which were added to the analysis on an explorative basis. A further aim of this study was to examine potential differences between patients who had planned stoma surgery (*'planned surgery patient group'*) versus patients who had to be operated on an emergency basis (*'emergency surgery patient group'*).

The following chapter will summarise the findings of this study. Firstly, treatment of data and the psychometric properties of the measures will be presented as well as the demographic and medical data information on participants in each group. Lastly, the results for the three hypotheses of this study are outlined.

TREATMENT OF DATA

Data were entered manually into SPSS and scanned for wrongly entered scores. Assumptions for using parametric statistical procedures were analysed and, if not otherwise stated, those assumptions were met and the appropriate parametric statistical procedures were used in the analysis.

Normality of distribution

In order to investigate the normality of the distribution of the data, skewness and kurtosis for all scores included in the analysis was analysed by transforming the scores from the SPSS output into z scores. A z score less than 2.58 indicates

that the distribution is normal enough to allow parametric testing. Table 2 provides statistics for skewness and kurtosis and the transformed z scores. No z scores was greater than 2.58 and therefore, it can be assumed that the distribution of scores across the scales used in this sample was normal enough to use parametric tests.

Table 2 Statistic for skewness and kurtosis

	Skewness			Kurtosis		
	Statistic	Standard error	z-score	Statistic	Standard error	z-score
HADS_Depression	0.65	0.31	2.07	0.13	0.61	0.46
HADS_Anxiety	0.47	0.31	1.52	-0.48	0.61	0.89
SHAI	0.03	0.31	0.11	-1.24	0.61	-1.42
SCSES_care	-0.23	0.31	-0.74	0.39	0.61	0.80
SCSES_social	-0.01	0.31	-0.05	-0.39	0.61	-0.80
SCSES_total	-0.14	0.31	-0.47	0.49	0.61	0.90
OAI_total	-0.41	0.31	-1.33	0.33	0.61	0.74

Note: HADS_Depression / Anxiety = Subscales of Hospital Anxiety and Depression Scale, SHAI = Short version of the Health Anxiety Inventory, SCSES_care / social / total = Subscales of Stoma Self-Efficacy Scale and total score, OAI_total = Ostonomy Adjustment Inventory

Regression and mediation analysis

Assumptions for using regression analysis were as outlined above (i.e. outliers, collinearity statistic) and no concerns were found in this respect. Mediation analysis were conducted based on suggestions by Frazier (2004) and by using the bootstrapping method suggested by Preacher and Hayes (2008) (SPSS macro downloaded from http://www.afhayes.com/spss-sas-and-mplus-macros-and-code.html#sobel).

Psychometric properties of measures

Conducting reliability analysis allowed the internal consistency of the self-report measures used in this study to be assessed. Table 3 summarises Cronbach alpha values for each instrument. Each scale showed good internal reliability indicating a consistency and accuracy of measurement in the constructs across the sample.

Table 3 Psychometric properties of measures used in the current study

	Crohnbach's alpha
Hospital Anxiety and Depression Scale	.89
Short Health Anxiety Inventory	.86
Stoma Care Self-Efficacy Subscale	.91
Stoma Social Self-Efficacy Subscale	.91
Ostonomy Adjustment Inventory	.89

CHARACTERISTICS OF PARTICIPANTS

Demographic and medical data

Table 4 separates medical data for the patient groups and provides mean and standard deviations for each group (see below). Firstly, mean and standard deviations for the whole sample are presented and group comparative results are presented.

The sample (N = 58) consisted of 31 male and 27 female patients undergoing surgery that resulted in a stoma. The planned surgery group (N = 32) had an equal number of female and male patients (N = 16 per gender), whereas there

were more male patients (N = 15) than female patients (N = 11) in the emergency surgery patient group (N = 26). The mean age in the sample was 64.09 (SD[1] = 14.62, Range = 19 – 90). Although the planned patients were slightly older (M[2] = 67.66, SD = 11.12, Range = 41 - 90) than emergency patients (M = 59.69, SD = 17.26, Range = 19 - 81) there were no significant differences between the groups (Mann Whitney U test performed, p[3] > .05). The majority were White British (96.6%) and over half of the sample was married (N = 37; 1 person was living with partner, 7 participants were single, 5 individuals were divorced and 7 were widowed). Thirty-four participants were retired and a quarter of participants (24.1%) were in full- or part-time employment. Seventeen patients had A-levels and a University degree.

Type of surgery, diagnosis, and time since surgery

The surgery was planned for 32 patients, whereas 26 patients had to be operated on an emergency basis. Of the overall sample, 35 patients (60.3%) were diagnosed with a type of cancer, whereas for a further seven patients medical investigations revealed benign tissue material. The remaining 16 patients had stoma surgery due to other medical conditions such as Diverticulitis, Ulcerative Colitis, and Crohn's Disease. At the time of assessment for the current study, patients have had their stoma for an average of 29 weeks (SD = 13.90, Range 6 –

[1] SD is the abbreviation for standard deviation

[2] M is the abbreviation for the mean

[3] p = is the abbreviation for the significance level

52 weeks). Planned surgery patients did not differ from emergency patients in the time that they had had their stoma ($t(47) = -1.46$, $p > .05$).

Time suffering from illness

The time patients had suffered from the illness that had led to stoma surgery varied greatly (Range = 2 weeks - 43 years) with an average time of suffering prior surgery of 29.43 months (M, SD = 86.88 months). Emergency patients differed from planned surgery patients in this respect (Mann Whitney U test performed, $p < .01$).

Burden of illness

On a scale of 1 to 10 where 1 symbolises illness symptoms that are not experienced as burdensome at all and 10 illustrates a profound level of burden due to symptoms, patients exhibited moderate levels of burden (M = 4.93, SD = 3.14). Group comparisons did not reveal differences between patients who had planned versus emergency surgery ($t(56) = .23$, $p > .05$).

Table 4 Medical data for planned surgery and emergency patient group

	Planned surgery patients	Emergency surgery patients
Diagnosis	Cancer N = 21 Benign N = 7 Other N = 4	Cancer N = 14 Other N = 12
Length of having stoma	M = 25.94 weeks, SD = 15.29 weeks	M = 31.67 weeks, SD = 11.66 weeks
Time suffering	M = 47.44 months, SD = 124.20 months	M = 11.00 months, SD = 13.31 months
Burden of illness	M = 5.03, SD = 3.18	M = 4.84, SD = 2.97

HYPOTHESIS 1: LOW LEVELS OF PSYCHOLOGICAL ADJUSTMENT ARE ASSOCIATED WITH HIGH LEVELS OF HEALTH ANXIETY AND LOW LEVELS OF STOMA CARE SELF-EFFICACY.

In order to test hypothesis 1, frequencies, means, and standard deviations, for these three variables were first examined. Then, a linear regression model was performed with health anxiety and stoma care self-efficacy as predictor and psychological adjustment as the outcome variable.

Psychological adjustment in stoma patients

The Ostonomy Adjustment Inventory defines psychological adjustment in stoma patients on 4 factors including acceptance of the stoma, pre-occupation with stoma, social engagement, and anger. Those variables are described as elements of adjustment rather than subscales that could be analysed separately. The authors also do not discuss clinically relevant cut-off points or categories but explain that higher scores indicate higher levels of adjustment. Scores can range from 0 to 92. The sample of stoma patients in this study scored on average 54.62 (M, SD = 14.93).

Health anxiety

Frequency of health anxiety in the sample

The health anxiety inventory collected data about: the level of worry about illness, perception of bodily sensations or changes, thoughts and mental images about illness, reassurance and relief, and risk perception in this patient group. SHAI scores, which can range from 0 – 42, were categorised and patients were allocated into one of three groups (hypochondriacal, high, and low / no health anxiety) based on their level of health anxiety. This was done by using the

suggested cut-off point of 15 for highly health anxious patients and 18 for hypochondriacal patients (Salkovskis et al., 2002).

More than a third of participants (N = 21, 36.2%) scored above the threshold for hypochondriasis and a further 9 participants were categorised as highly health anxious, whereas the other half of the sample (N = 28, 48.3%) scored in the low range for health anxiety or had no elevated levels. On average, the sample had an overall score of 14.62 (M, SD = 6.73), just below the cut-off for high health anxiety.

Negative consequences – 'costs' – of illness

The second part of the SHAI asked participants to think about a serious illness they might develop in the future and to consider: if they would still enjoy life despite illness, if they would believe medicine could cure them should they develop an illness, if a serious illness would ruin their life, and if a serious illness would cost them their dignity. Participants were specifically instructed to think about their future and not consider their current circumstances primarily. Overall, scores can range from 0 – 12 (higher scores indicate higher levels of perceived costs of illness). The mean score in this sample was 3.50 (M, SD = 2.36) suggesting moderately low perceived costs of future illnesses.

Stoma self-efficacy

The stoma self-efficacy scale has two subscales: stoma care (scores range from 0 – 52) and dealing with social aspects (scores range from 0 – 45). Higher scores indicate higher levels of self-efficacy. Respondents choose one in five categories ranging from 'not all confident' to 'extremely confident'.

Overall, patients in this sample scored moderately low on the scales. On average, patients had a score of 29.00 (M, SD = 9.97) on the stoma care self-efficacy scale and an average score of 18.00 (M, SD = 8.56) on the stoma social self-efficacy subscale.

To reiterate, the subscales have been found to be highly correlated (r = .73, (Bekkers et al., 1996)), which can pose the threat to a regression model by destabilising the coefficients. Some authors have therefore decided to only use one subscale based on their study aims (Simmons et al., 2007). We decided to investigate the relationship between the subscales and the outcome in separate regression models.

The two subscales had a smaller correlation coefficient than found in previous research (r = .547) yet the correlation was significant ($p < .01$). Stoma care self-efficacy correlated more highly with adjustment (r = .549, $p < .01$) than stoma social self-efficacy (r = .439, $p < .01$). Preliminary regression analysis suggested that stoma care self-efficacy explained about 30% of the variance in adjustment (adjusted R^2 = .29; F (1,52) = 24.19, p = .000) and was a significant predictor for the outcome (B = .82, β = .54, t(56) = 4.91, p = .000). Stoma social self-efficacy, on the other hand, only explained approximately 18% of the variances of scores in psychological adjustment (adjusted R^2 = .17; F (1,56) = 13.36, p = .001). Nevertheless, it was a significant predictor (B = .76, β = .43, t(56) = 3.65, p = .001).

Based on these preliminary findings, which show that the predictive value of stoma care self-efficacy for psychological adjustment in stoma patients is likely to

be higher, it was assumed that this scale will have higher predictive value for the outcome. However, the regression model was tested, separately, with both subscales of the stoma self-efficacy scale.

Health anxiety and stoma self-efficacy as predictors for adjustment

Prior to the main analysis, correlation coefficients between the three variables were investigated. Both predictor variables significantly correlated with the psychological adjustment (health anxiety r = -.47, $p < .01$; stoma care self-efficacy r = .54, $p < .001$; stoma social self-efficacy $p < .01$). These correlations also occurred in the direction that was anticipated in this study. The predictor variables were also correlated. It was found that health anxiety and stoma care self-efficacy (r = -.39, $p < .05$), as well as health anxiety and stoma social self-efficacy (r = -.58, $p < .01$), were significantly correlated. The collinearity statistic produced a VIF value of 1.01 for stoma care self-efficacy and of 1.51 for stoma social self-efficacy. Both values were below 10 (scores above are suggested as problematic). Also the tolerance level within the collinearity statistic were below 0.1, which gives further support for including the proposed predictors without destabilising the regression model.

Consequently, based on these preliminary steps in the analysis, it was appropriate to run a multiple regression analysis to investigate the predictive value of health anxiety and stoma self-efficacy for psychological adjustment in stoma patients.

The overall model fit was significant. The two variables – health anxiety and stoma care self-efficacy – accounted for a significant amount of variances in psychological adjustment in stoma patients (adjusted $R^2 = .38$; $F(2,55) = 18.53$, $p < .001$). The partial regression coefficients showed that health anxiety had a significant unique contribution to adjustment. Stoma care self-efficacy was also independently associated with adjustment after controlling for health anxiety.

In a second model, using the social subscale of the stoma self-efficacy measures, health anxiety no longer had a unique contribution to the overall significant model for adjustment (adjusted $R^2 = .20$; $F(2, 55) = 8.34$, $p < .001$). A tabulated summary of regression results is added at the end of this section (see table 5 below).

Based on these findings, hypothesis 1 investigating health anxiety and stoma care self-efficacy as predictors for adjustment to stoma was supported by the data. It appears that lower levels of adjustment are associated with higher levels of health anxiety and lower levels of self-efficacy beliefs about caring for the stoma.

Table 5 Summary of regression results

	B	SE B	95% CI	β	t - statistic
Model 1					
Health anxiety	-.61	.20	-1.01, -.21	-.33*	t = -2.37; p = .02
Stoma care self-efficacy	.67	.16	.34, .91	.45**	t = 4.59; p < .000
Model 2					
Health anxiety	-.47	.28	-1.03-.08	-.21	t = -1.69; p = .10
Stoma social self-efficacy	.62	.22	.17-1.06	.36*	t = 2.80; p = .001

Note: B = unstandardized regression coefficient, SE B = standard error B, CI = confidence interval, β = standardised regression coefficient, * p < .05, ** p < .001

Further exploratory analyses

Ancillary analyses were performed to further understand the relationship between the predictor and outcome variables and to consider additional factors that may explain psychological adjustment in stoma patients. Satisfaction with pre-operative preparation, severity of illness (i.e. experience of burden), and time since surgery were explored as potentially influential variables and entered as a first step into a stepwise regression model before adding health anxiety and stoma care self-efficacy. This was done to investigate whether the variables of main interest in this study have predictive value for stoma adjustment after controlling for the influence time may have had on the adjustment process as well as the level of burden experienced by patients, and their satisfaction with preparation for surgery.

The regression result showed that all three variables did not contribute to the model at all. As they were not significantly related to stoma adjustment, time, burden, and satisfaction were statistically excluded from the model (Field, 2009). Thus, the findings show that over and above the variables we controlled for in the model, health anxiety and stoma care self-efficacy predict stoma adjustment.

The results of the stepwise regression model further clarified that self-efficacy appears to be the strongest predictors for adjustment and explains 29.2% of the variance in the outcome (adjusted R^2 of model 1 including stoma care self-efficacy as predictor for adjustment; $F(1, 48 = 20.80, p < .001)$. An additional 10.2% of variance is explained by adding health anxiety to the model (R^2 change of model 2 including stoma care self-efficacy and health anxiety; $F(2, 46) = 15.87, p < .001$; adjusted $R^2 = .383$). The change statistic from model 1 model 2 was also significant ($F(1, 46) = 7.89, p < .01$).

In summary, the results show that health anxiety and stoma care self-efficacy are significant predictors of adjustment to a stoma after controlling for the time since operation, pre-operative burden of symptoms, and satisfaction with preparation for surgery, which all do not seem to contribute to the overall model fit.

HYPOTHESIS 2: HEALTH ANXIETY MEDIATES THE RELATIONSHIP BETWEEN STOMA SELF-EFFICACY AND ADJUSTMENT

Mediation model

Heath anxiety was examined as a mediator for the relationship between stoma care self-efficacy and stoma adjustment. As the second regression model

including the social subscale of the self-efficacy measure did not show health anxiety to be of unique association with the outcome, the following variables were chosen and the model was tested including health anxiety as mediator of the relationship between stoma care self-efficacy and psychological adjustment. The model as outlined in Figure 5 was the hypothesised mediation model tested in this study.

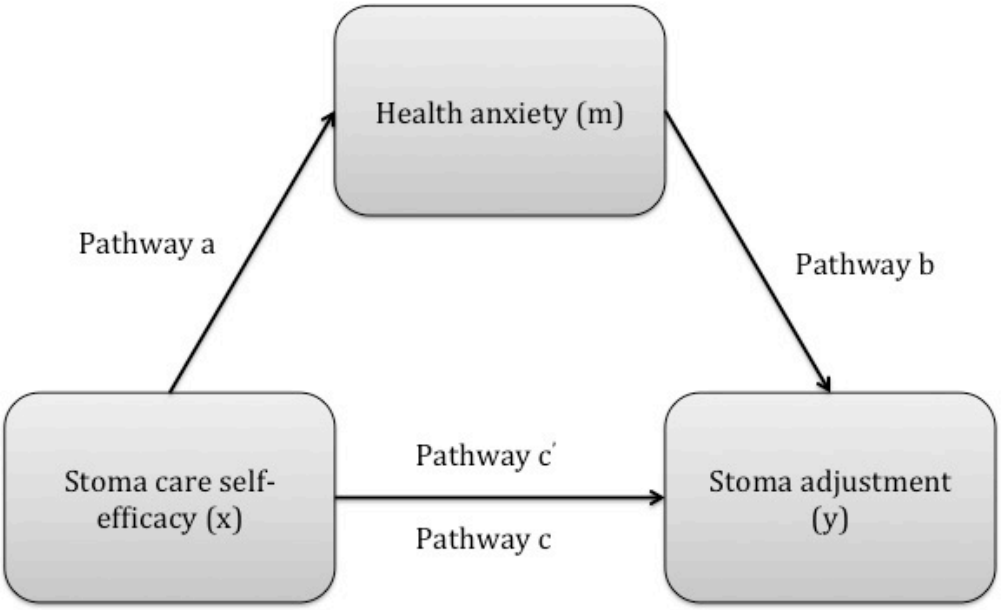


Figure 5 Hypothesised mediation model including the independent variable (stoma care self-efficacy = x), the mediator (health anxiety = m) the outcome (stoma adjustment = y)

Mediation was tested by regressing the dependent variable (i.e. stoma adjustment) on stoma care self-efficacy in the presence of health anxiety. The analyses used 5000 bootstrap samples. Figure 6 illustrates the estimated coefficients for the analysis.

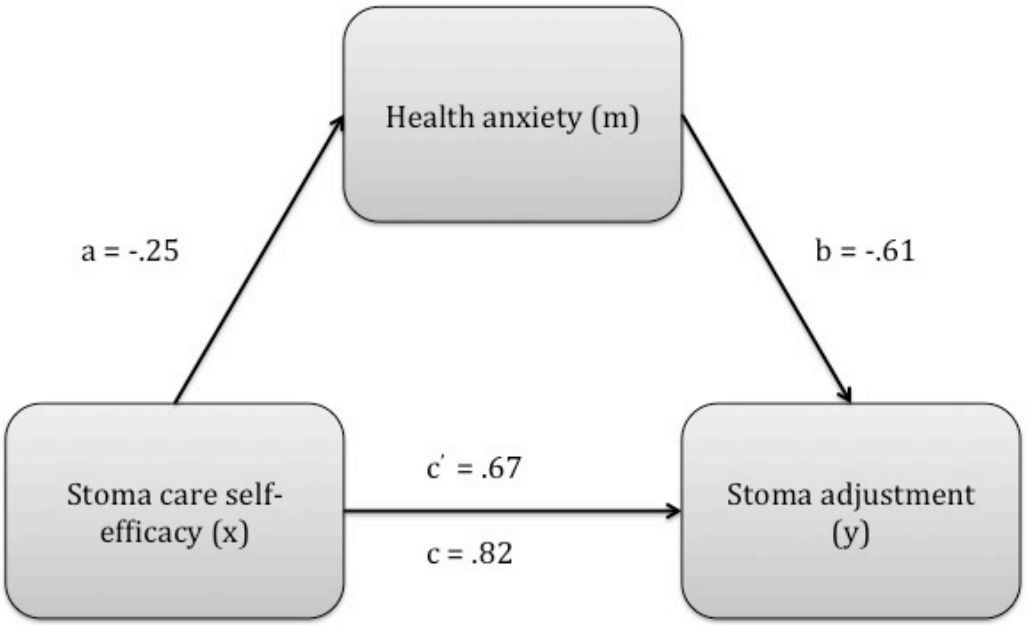


Figure 6 Results for mediation analysis (N = 58)

Results confirmed the existence of a mediation effect of stoma care self-efficacy on stoma adjustment via health anxiety and thus, hypothesis 2 was supported by the current set of stoma patient data (see Table 6). However, the results showed that there is partial, but not full mediation, because the effect between self-efficacy and adjustment is not zero when fixing the predictor variable health anxiety (Preacher & Hayes, 2008). The value of the indirect effect of health anxiety was calculated with the following formulas (Preacher & Hayes, 2008):

$B_{\text{indirect}} = B_{(a)} * B_{(b)}$ = -.25 x -.61 = .15 and $B_{\text{indirect}} / B_{\text{total}}$ = .15 / .82 = .1829

Thus, health anxiety explained 18.29% of the relationship between stoma care self-efficacy and stoma adjustment. The complete model (including the

mediator and predictor variable) explained 38.09% of the variance in stoma adjustment ($F(2, 55) = 18.54$, $p < .001$), which is a large effect (Fairchild, Mackinnon, Taborga, & Taylor, 2009).

Table 6 Coefficients of the model testing the mediating role of health anxiety in the relationship between stoma care self-efficacy and stoma adjustment

Model	Estimate	SE	95% CI	*p*-value
SE → HA (a)	-.25	.10	-	< .05
HA → Adj (b)	-.61	.20	-	< .01
SE → Adj (c)	.82	.17	-	< .001
Adj. R^2 (y, x)	.18	-	-	-
SE → Adj via HA (c')	.67	.16	-	< .01
Indirect effect (a x b)	.15	.08	.03 - .36	< .01
Adj. R^2 (m, x)	.08	-	-	-
Adj. R^2 (y, m, x)	.38	-	-	-

Note: SE = stoma care self-efficacy (independent variable x), HA = health anxiety (mediator variable m), Adj = stoma adjustment (outcome variable y); Estimates = either B (unstandardized regression coefficient) for pathway analyses or F value for overall model fit; SE B = standard error B, CI = confidence interval; Adj. R^2 (y, x) is the proportion of variance explained in y by x; Adj. R^2 (m, x) is the proportion of variance explained in m by x; Adj. R^2 (y, m, x) is the proportion of variance explained in y by x and m; the 95% Confidence Interval (CI) for indirect effect (a x b) was obtained by the bias-corrected bootstrap with 5000 samples

HYPOTHESIS 3: EMERGENCY PATIENTS FEEL LESS PREPARED FOR SURGERY, HAVE HIGHER LEVELS OF HEALTH ANXIETY, LOWER LEVELS OF STOMA SELF-EFFICACY, LOWER LEVELS OF ADJUSTMENT, AND HIGHER LEVELS OF OVERALL DISTRESS.

Level of preparedness for surgery

Participants' ratings of their satisfaction with pre-surgery preparation demonstrate that emergency patients only partially feel less prepared for their operation. Generally, emergency and planned surgery patients did not differ significantly in their levels of preparedness for surgery on the overall satisfaction score.

Further item-by-item analyses showed that there was a significant differences between the groups in respect of (i) being involved in the decision making process around having to have stoma surgery, such that individuals in the planned surgery group were more satisfied (M = 7.64, DS =3.11) than individuals in the emergency surgery group (M = 5.61, SD = 3.13) ($t(56) = 2.38$, $p < .05$, d[4] = .66) and (ii) satisfaction with information why a stoma was needed, such that individuals in the planned surgery group were more satisfied (M = 8.32, DS =2.74) than individuals in the emergency surgery group (M = 6.67, SD = 2.97) ($t(56) = 2.20$, $p < .05$, $d = .56$). However, in order to adjust for multiple testing using Bonferroni correction, these results are not significant based on the adjusted significant level for 6 group comparisons of $p < .0083$.

[4] Cohen's d effect size

Table 7 summarises means, standard deviations, and tests statistics for the patients' satisfaction with pre-operative preparation.

Table 7 Group comparison (planned n = 32 versus emergency surgery n = 26) for satisfaction with pre-operative preparation

Items[5]	Surgery type	M	SD	Test Statistic
Overall satisfaction.	Planned	8.17	2.44	t(56) = 1.22, p = .23
	Emergency	7.43	2.31	
Satisfaction with being involved in decision around having surgery.	Planned	7.64	3.11	t(56) = 2.38, p = .02, d[6] = .66
	Emergency	5.61	3.13	
Satisfaction with information why stoma is needed.	Planned	8.32	2.74	t(56) = 2.20, p = .03, d = .56
	Emergency	6.67	2.97	
Satisfaction with information to look after stoma.	Planned	8.25	2.85	t(56) = -.55, p = .59
	Emergency	8.66	1.93	
Satisfaction with feeling prepared for negative physical aspects.	Planned	7.62	2.67	t(56) = 1.37, p = .17
	Emergency	6.87	2.05	
Satisfaction with feeling prepared for negative psychological aspects.	Planned	6.99	3.31	t(56) = .93, p = .36
	Emergency	6.12	2.33	

[5] All items ranged from 0-10

[6] Cohen's d effect size

Health anxiety

Patients, who had planned stoma surgery, had slightly higher levels of health anxiety (M = 15.62, SD = 6.41) in comparison to emergency patients (M = 13.38, SD = 7.10), but there were no significant differences between the groups ($t(56) = 1.27$, $p > .05$). Planned surgery patients scored slightly higher on the costs of illness items (M = 3.81, SD = 2.59) than emergency patients (M = 3.11, SD = 2.02) but the groups did also not differ from each other significantly ($t(56) = 1.12$, $p > .05$). Thus, hypothesis 3 was not supported by the data.

Stoma self-efficacy

Group comparisons indicated that patients, who had planned stoma surgery, had significant lower levels of self-efficacy in dealing with social aspects of the stoma (i.e. talking to people about the stoma or spending time away from home) (M= 15.22 (SD = 7.91), than emergency patients (M = 22.18, SD = 7.73) ($t(56) = -3.30$, $p < .001$, $d = .9$). This difference between the groups had a large effect.

There were no differences between the groups on the stoma care subscale ($t(56) = -1.22$, $p > .05$). Based on these findings, hypothesis 3 was also not supported by the results.

Psychological adjustment to stoma

It was hypothesised that emergency patients have lower levels of adjustment yet the data suggests that they in fact have higher levels (M = 58.23, SD = 14.25) compared to patients with planned surgeries (M = 51.77, SD = 15.01) but the groups do not differ significantly from each other ($t(56) = -1.68$, $p > .05$). Thus,

there was no evidence for the proposed hypothesis based on the data of this sample.

Overall levels of psychological distress in patients

Overall, approximately one third of the patients in this study appear to suffer from clinical levels (score greater than 11) of depression (N = 8) and anxiety (N = 11) based on their scores on the scale. Elevated, but not clinical, symptom levels (score greater than 8 smaller than 11) were found for 14 patients on the depression scale and 9 patients on the anxiety subscale. For both subscales of the HADS, 36 of 58 patients (62.1%) had no clinical levels of depression or anxiety.

Group comparisons showed that there were no significant differences between emergency and planned surgeries on their levels of depression and anxiety, as illustrated in Table 8.

Table 8 Group comparison (planned n = 32 versus emergency surgery n = 26) for depression and anxiety

		M	SD	Test Statistic
HADS Depression	Planned surgery	6.54	4.33	t(56) = .96,
	Emergency surgery	5.48	4.45	p = .34
HADS Anxiety	Planned surgery	7.12	4.14	t(56) = 1.06,
	Emergency surgery	6.01	3.78	p = .29

CHAPTER 4: DISCUSSION

This final chapter will summarise the main findings of this study and discuss them against the background of existing research in the context of stoma surgery and adjustment. The theoretical and clinical implications of this study will be elaborated as well as the limitations that might impact on the results of the study.

REITERATION OF AIMS AND RATIONALE OF THESIS

The rationale behind this thesis was to investigate the needs and potential risk factors for poorer adjustment in patients who suffered serious health conditions and had to undergo stoma surgery as part of their treatment. The aim was to explore the variables considered to be related to adjustment to stoma in this patient population. By exploring these potential risk and protective factors, it was hoped to provide information that can be used by health care professionals offering care and support to this group of patients.

The study described in this thesis was carried out to investigate health anxiety in a sample of patients undergoing either planned or emergency surgery that resulted in a stoma. The hypothesis was tested as to whether higher levels of health anxiety and lower levels of stoma self-efficacy predict lower stoma adjustment scores in patients. The study also tested whether patients with higher levels of health anxiety have significantly lower levels of adjustment than patients who did not present with clinical levels of health anxiety.

Several factors were considered to potentially influence the proposed model. The following variables were added to the regression model: burden of illness symptoms prior to the surgery as a measure for severity of illness, the time that

had passed since surgery, and the level of preparedness for the stoma. The over-and-above explanation of variance in adjustment was tested by adding the main variables of interest (i.e. health anxiety and self-efficacy) in a second step to the regression model and testing their contribution to it after controlling statistically for the influence that time, burden, and preparedness may have on the overall model.

Moreover, the study examined the processes that might be involved in stoma adjustment by exploring the mediating effect health anxiety might have on the relationship between stoma self-efficacy and psychological adjustment in patients. The third aim was to investigate differences in feelings of preparedness for surgery, health anxiety, stoma self-efficacy, adjustment, and general distress in patients undergoing emergency versus planned stoma surgery. It was hypothesised that emergency patients will struggle more than patients undergoing planned surgery.

This study had a cross-sectional design and used validated and reliable self-report measures. Participants for the study were recruited from a NHS setting and internet-based websites and support groups. A total of 58 patients completed the assessment.

SUMMARY OF MAIN FINDINGS

Health anxiety and its role in adjustment to stoma

This study supports the hypothesis that high levels of health anxiety are a predictor for maladjustment in stoma patients. Health anxiety was highly frequent in this sample with 51.7% scoring in the clinical range for health

anxiety. Patients with high levels of health anxiety had significantly lower adjustment scores than patients who did not present with clinical levels of health anxious cognitions and beliefs. This result provided support for hypothesis 2.

In addition to stoma care self-efficacy, health anxiety was a significant predictor of stoma adjustment and both variables explained almost 40% of the variance in the outcome variable. Further analysis showed that stoma care self-efficacy was the strongest predictor in this model and that health anxiety added about 10% to the overall variance explained in the model. Health anxiety made a significant contribution to the model, which was evident in the significant change statistic from model 1 including only self-efficacy to model 2 including both self-efficacy and health anxiety.

Time since surgery, the burden patients had experienced due to their illness, the level of preparedness for surgery, and living with a stoma, did not contribute to the explanation of the variation in adjustment scores. Stoma care self-efficacy and health anxiety were significant predictor of stoma adjustment even after controlling for these variables.

The hypothesised process model testing health anxiety as the mediator of the relationship between stoma care self-efficacy and stoma adjustment was also supported by the findings of the mediation analysis. The results indicated that higher levels of stoma care self-efficacy are associated with lower levels of health anxiety. Highly anxious patients, on the other hand, appear to have lower adjustment scores. The process between self-efficacy and adjustment was investigated by testing whether health anxiety influences the pathway and,

indeed, it seems to mediate the relationship. However, the results show that the mediation is partial, which means that the relationship between self-efficacy and adjustment remains significant even when controlling for the impact health anxiety might have on it.

Differences in emergency and planned surgery patients

Overall, the two patient groups felt both well prepared for their surgery and rated their satisfaction with stoma care and nursing prior to their operation as high. However, emergency patient felt less involved in the decision making process around having a stoma and were also less satisfied with the communication about why the stoma was needed.

Levels of health anxiety in both patient groups were moderately high but they did not differ from each other. They also had similar levels of stoma adjustment. Emergency and planned surgery patients did not differ in their levels of overall distress. Just under half of the sample had elevated or clinical levels of distress. In respect of stoma care self-efficacy, patients had moderately low levels of overall self-efficacy. Patients did not differ in their self-efficacy beliefs in respect of stoma care, but, in contrary to the hypothesis, planned surgery patients had lower self-efficacy in regards to how to deal with the social aspects arising.

In summary, the findings show that some patients adapt well to living with a stoma. High self-efficacy beliefs about coping resources seems to be of particular importance and might be a protective factor for positive adjustment in stoma patients. On the other hand, the results of this study indicate that high levels of health anxiety are associated with lower adjustment to stoma and it appears that

health anxiety might have a detrimental impact on the relationship between stoma self-efficacy and adjustment. The data supported the hypothesis that lower self-efficacy might be related to high health anxious thoughts and feelings and this, in turn, is associated with less adjustment in stoma patients.

CONTRIBUTION OF THESIS TO EXISTING BODY OF KNOWLEDGE AND THEORETICAL IMPLICATIONS

Frequency of health anxiety in stoma patients

This study has provided data for the frequency of health anxiety in a sample of stoma patients. In line with previous research (Barrett et al., 2012; Rode et al., 2006; Tyrer et al., 2011), the study has shown that a substantial amount of patients suffer from clinical levels of health anxiety. The current study has helped to understand that health anxiety might be an issue for some patients undergoing stoma surgery, a population that has not been examined in this context. It might be that health anxiety is indeed high in stoma populations and epidemiological studies should endeavour to provide further clarification about the prevalence of health anxiety amongst stoma patients.

Health anxiety as a risk factor for maladjustment in stoma patients

The review of the literature illustrated that living with a stoma can have a profound impact on body image (Jenks et al., 1997; Salter, 1997), interpersonal relationships (Nordstrom & Nyman, 1991; Persson & Hellström, 2002; Salter, 1992a), and quality of life (Orsini et al., 2013; Salles et al., 2014; Salomé et al., 2014; Taylor & Morgan, 2011). Patients exhibit negative affect and it appears that negative cognitions and beliefs about the stoma play a role in this regard

(White, 1998; White & Unwin, 1998). The current study adds to these findings by demonstrating how health anxious cognitions and emotions are associated with poorer adjustment, which was measured with a stoma specific measure in this study. After controlling for the time since surgery, pre-operative burden of symptoms, and preparedness for surgery, which all did not significantly predict for adjustment, both health anxiety and self-efficacy were found to be associated with the variability of adjustment scores in stoma patients. The following section discusses theoretical implications from the current study.

Possible processes of maladjustment in health anxious stoma patients

To reiterate, the cognitive model of health anxiety (Salkovskis, 1996c; Salkovskis et al., 2002; Salkovskis & Warwick, 1986) postulates that bodily signs and symptoms, and medical information, are evaluated considering the probability of threat and awfulness of illness in addition to personal coping resources. Highly health anxiety individuals are more likely to interpret bodily sensation and medical information as threatening and this threat appraisal becomes the major cause for changes in mood and physical arousal associated with anxiety. Safety seeking behaviours such as avoidance, checking, and reassurance seeking, operate to maintain the vicious cycle of anxiety and maladaptive coping.

Because of the nature of health anxiety, patients who exhibit higher levels of health anxiety might find it particularly difficult to keep their mind off the stoma and continue to worry about it. They might have a heightened awareness of bodily sensations and are preoccupied with their stoma. The physical arousal associated with anxiety is likely to impact the digestive system, which can have a

direct influence on how the stoma is experienced. Commonly found safety seeking behaviours such as avoidance may lead to avoiding taking care of the stoma or avoiding social contact. Feelings of personal control over the stoma have been found to be protective for patients' adaptation post surgery (Simmons et al., 2007; White, 1998, 2010; White & Unwin, 1998). Social support has been found in many studies to be of crucial importance (Nausheen et al., 2009; Nugent et al., 1999; Paterson et al., 2015; Persson & Hellström, 2002).

Stoma patients have to process a considerable amount of medical information and learn new skills after their surgery in respect of how to handle the stoma. For someone with high levels of health anxiety, it might be that this information is understood in a way that is unhelpful for acquiring the necessary skills set to live well with the stoma. For example, highly health anxious patients may misinterpret information about the stoma such as how to take care of the skin around the stoma, nutritional advice, and changes in their digestive system including symptoms to be aware of, as threatening in respect of developing new health issues and/or general complications.

Stoma patients also experience different bodily symptoms and people with higher levels of health anxiety might be more likely to misinterpret these symptoms to their own detriment. For example, irregular bowel functioning may be interpreted as 'the bag will leak and I won't cope'. This may in turn lead to increased checking of the bag, or increased awareness of bodily symptoms.

Patients may also find information about their cancer diagnosis and prognosis (for instance) after surgery difficult to comprehend in a non-

threatening way. Threat appraisal has be linked with emotion-focused coping (Lazarus, 2006; Lazarus & Folkman, 1984), which in many cases is associated with safety seeking behaviours that are likely to maintain the vicious cycles health anxious individuals feel trapped in (Warwick & Salkovskis, 1989, 1990).

In summary, because of all of these possible processes, it is likely that highly health anxious individuals remain preoccupied with their stoma and their underlying condition and therefore, might struggle with coming to terms with their stoma and accepting it; this is a factor that was found to be protective for adjustment (Simmons et al., 2007).

The current study has shown that health anxious patients are less likely to adjust well to their stoma. However, future studies should pay attention to the specific safety seeking behaviours that might be playing a role here and were not assessed with the Short Health Anxiety Inventory in the current study. Safety seeking behaviours should be measured in a specific way, relevant to stoma patients.

Moreover, qualitative research may enhance the understanding of how a health anxious person experienced living with a stoma and what their particular difficulties are. Despite the need for future research, this study has helped to understand the role of health anxiety in stoma patients and can offer clinical implications, which are discussed below.

Self-efficacy as a protective factor for stoma adjustment

In line with previous research (Bekkers et al., 1996; Bekkers et al., 1997; Bekkers et al., 1993; Simmons et al., 2007), higher self-efficacy beliefs in respect

of coping with the stoma were related to higher levels of adjustment. The protective nature of self-efficacy has been demonstrated in many studies (Paterson et al., 2015; Simmons et al., 2007; Zhang et al., 2014; Zhang et al., 2015) and the current research adds to the evidence base for this construct in the context of stoma adjustment. Bandura (1992) distinguishes between four processes through which human functioning is regulated by self-efficacy beliefs, as illustrated in Table 9.

Table 9 Self-efficacy processes of human functioning

Cognitive processes	Self-efficacy and cognitive stimulation of execution of activities affect each other bi-directionally: people with low efficacy beliefs are more inclined to visualise failure scenarios and might dwell on how things could go wrong.
Motivational processes	In cognitive motivation, people motivate themselves and guide their actions anticipatorily through the exercise of consideration of future events.
Affective processes	Self-efficacy beliefs influence the nature and intensity of emotional experiences.
Selective processes	Judgments of personal efficacy shape developmental courses and paths by influencing the selection of activities and environments.

Bandura explains that self-efficacy beliefs in respect of emotion regulation can be related to attentional bias and influence how stressful events are cognitively represented. Perceived self-efficacy for exercising control over potentially threatening situations plays a central role in anxiety arousal, whereby the appraisal of having efficient coping strategies mediates this relationship.

Individuals, who believe they cannot manage a stressful situation, dwell on coping deficiencies thereby distressing themselves, and their level of functioning becomes impaired. This corresponds with theories that emphasise the influence of helplessness in the context of depression and psychological impairment (Klein, Fencilmorse, & Seligman, 1976; Lazarus, 2000; Seligman, 1972).

The current study has not only replicated findings from previous research illustrating the crucial role of self-efficacy for adjustment in stoma patients (Bekkers et al., 1996; Bekkers et al., 1997; Bekkers et al., 1993; Simmons et al., 2007) and added to its evidence; the study has also investigated the interplay between self-efficacy and health anxiety and its impact on adjustment. The mediation analysis showed that there was a significant indirect effect of health anxiety on the relationship between self-efficacy and stoma adjustment. Levels of health anxiety explained almost 20% of the variance of the relationship between these two variables. Thus, the current study has enhanced the understanding of health anxiety and how it interacts with self-efficacy and has important clinical implications as discussed below.

Preparedness for surgery as a factor for adjustment to stoma

Patients rated their satisfaction with pre-operative preparation as very high; yet this did not correspondent with their adjustment scores (i.e. preparedness ratings did not predict adjustment scores). It should be discussed whether the way preparedness was measures was sufficient in understanding the true nature of the concept. For example, the items used in this study covered broad categories such as feeling prepared for physical or psychological implications. The assessment may have benefitted from a more specific assessment. For

example, future studies could explore these concepts qualitatively to gain further insight. In addition, the majority of patients in this study were recruited from one specific hospital site. Bias due to social desirability may have also impacted on the high ratings of satisfaction with preparation for surgery. Thus, the question remains open whether pre-operative preparation was sufficient in helping patients to adjust after surgery. Ideas about how to facilitate self-efficacy, normalise anxiety and even consider anxiety as a protective factor are discussed later in this chapter.

Differences between emergency and planned stoma surgery patients

Differences in patients undergoing emergency versus planned surgery and how this may impact patients psychologically has not found much attention yet in stoma populations. Research to date showed that emergency patients surgically treated for cancer have poorer prognosis. The disease is often more advanced and they are admitted to hospital more frequently (Amri et al., 2015; Dekker et al., 2014; Kenig & Richter, 2013; Santos et al., 2014). Based on those findings, the study tested the hypotheses that emergency patients are doing less well psychologically in comparison to planned surgery patients, yet the results suggest the opposite. Patient groups largely did not differ from each other. Statistical power may have an impact on that as well and the possibility that they are presenting in a similar manner. Interesting, although not significantly different from emergency, planned surgery patients appeared to present with more psychological morbidity.

Further research is necessary to shed light on whether the mode of surgery impacts on adjustment in stoma patients. Future research should attempt gathering more detailed medical information such as an illness history and past treatment experiences. It could also be possible that emergency patients after years of medical treatment and hospital admissions get used to processes involved in their treatment.

METHODOLOGICAL CONSIDERATIONS, LIMITATIONS, AND STRENGTHS

The study has limitations that are important to consider against the background of interpreting its results.

Sampling and recruitment

Participants of this study were not randomly selected from the population of stoma patients. Self-selection can lead to biases in findings as participants might be motivated to take part for reasons the research cannot control for. For example, patients, who were approached by the stoma care nurses shortly before their surgery, declined to take part later on and it is possible that this group was particularly struggling and did not feel able to, or wanted to, disclose how they were coping with living with a stoma. The patients may have also felt obliged to take part as they were recruited in the hospital setting they were about to have their stoma surgery. Similarly, other motivational patterns may be true with those that did take part but which don't correspondent to a representative sample of the underlying population.

It would have been an advantage to formally collect data of the reasons for their negative response and future studies should attempt to do so.

To re-iterate, patients were approached sensitively and it was explained in great detail that participation was not related to their care in hospital and post-surgery in any way.

It was estimated that there were about 100 – 150 surgeries a year. Thus, the number of approached patients suggests that the estimate was largely correct. We did not, however, account for such a great rate of patients declining later on to participate. As it was hoped to conduct a longitudinal study, these recruitment challenges show that a much longer recruitment phase might be necessary for such research endeavours.

It could have enhanced the implications of the results if a control group would have been recruited. For example, data of a group of patients undergoing invasive, but not stoma surgery, and a group of patient with a cancer diagnosis but no surgery, in addition to the sample recruited for the purpose of this study, could have helped to study adjustment and predictive factors specific to stoma adjustment in more detail. Future studies could collect control group data to investigate differences between diagnoses.

Nevertheless, this was the first study investigating health anxiety in a sample of stoma patients. A large number of patients were approached for the study and it was possible to recruit the sample size that was estimated as necessary, based on the power analysis, for the analyses of this study.

Assessment and statistical analysis

This study used self-report measures, which have several limitations. First, self-report questionnaires cannot capture all facets of human behaviour in a way

qualitative research is able to take interpersonal nuisances and subtle differences into account. On the other hand, the questionnaires used in this study have been chosen because they have excellent psychometric properties and have been found to reliably assess the constructs of interest. Reliability analysis within this set of data confirmed the psychometric value of the assessments tools used in this study.

However, self-report measures rely on participants responding openly and truly and cannot control for responses that might also be influenced by expectations such as social desirability, which can negatively impact on the validity of findings (Clark-Carter, 2010). More idiosyncratic accounts from participants such as those collected with qualitative research may be a helpful addition to quantitative data and would also address the limitations due to social desirability. Future study using a qualitative design could investigate the idiosyncratic accounts and perceptions of patients living with a stoma and collect valuable information about their needs as a patient group.

Two of the questionnaires used in this study (i.e. Short Health Anxiety Inventory and Ostonomy Adjustment Inventory) may include items that potentially overlap in what they measure. The OAI-23 has a subscale named 'anxious pre-occupation with the stoma'. On the other hand, some of the SHAI items are concerned about pre-occupation with health and illness and related information. Thus, it has to be mentioned that parts of the SHAI and OAI-23 could overlap on a construct level and it would have been an advantage to further explore this and to conduct the analyses without the respective OAI-23 subscale.

This approach was not taken because of the problems this would have had for the validity and reliability of the inventories.

It was chosen to offer participants to the choice to complete the questionnaires together with the researcher (as a fully structured interview) or alone. This decision was based on ethical consideration. The patients who took part in the study had, or are still suffering from, an often life threating illness and underwent invasive surgery with a long recovery time. Thus, it was considered to be especially important to approach participants sensitively and offer choice when taking part in the research and it could be seen as strength of this study. It might be an advantage in future studies to decide on one mode of collecting data and completing the assessment with all patients as a structured interview. However, as previously stated, it seemed ethical to provide a choice to participants. Moreover, patients, who prefer to complete the questionnaire on their own, may then decide not to take part.

Type I and Type II error are important limitations to consider in psychological research. Type I error describes a false positive result, which means the null hypothesis is wrongly rejected. Thus, a Type I error is related to the detection of an effect when there is actually none in the population (Clark-Carter, 2010). Multiple testing inflates the risk of Type I error and it becomes important to control statically for it by using the appropriate procedure such as one way analysis of variance with corrections (i.e Bonferroni) for multiple testing when comparing, for example, three groups. The issue to consider being that because more tests are carried out there is a higher risk of finding a significant

result by chance alone (Field, 2009). In contrast, Type II relates to a false negative result, or in other words, the failure of detecting an effect in a population. Type II errors are related to underpowered research and power analyses which would otherwise help to estimate how many participants are approximately necessary to detect a potential difference. Power analyses were used in this study to inform the sampling process.

Design

This study was initially designed as a longitudinal study. It was intended to collect data before the surgery, and six weeks and 3 months after the operation. We wanted to test the hypothesis whether pre-surgery health anxiety levels predict post-surgery stoma adjustment. Given the time frame of this study and the necessity to complete the project within a constrained schedule, it was not possible to collect sufficient data for a longitudinal design.

However, an additional difficulty, which was not expected to be so profoundly challenging, was related to the recruitment itself. Patients, recruited as part of the prospective sample, which was set up to collect longitudinal data, dropped out to a large degree after initial contact was established. Only five out of 25 patients recruited by the stoma nurses completed the questionnaire. There were several reasons for this high dropout rate and these were discussed previously.

This shows that patients recruited around the time of their stoma surgery are faced with many challenges and even a very sensitive approach by the clinical team they are familiar with may be not enough to engage this patient group. It is likely that a post-surgery assessment is not feasible and longer follow up periods

are necessary in future studies to capture adjustment processes in these patients. Furthermore, a pre-surgery assessment proved to be impossible because by the time the researcher had received contact details most patients have had their operation.

From a feasibility point of view, we can learn from this study that longitudinal research involving stoma patients is challenging. Pre-surgery assessment may need to be completed by the clinical staff, who has direct and immediate access to the patient. Approaching patients shortly after their surgery may not be appropriate as this initial time adjusting to living with a stoma may be one of the most challenging both physically and psychologically and patients might therefore not feel able to take part in research projects. Assessments at a later stage might be more successful in terms of gathering data and recruitment rates.

The cross-sectional design of this study has impacted on the conclusions that can be drawn from the results. No causal conclusion can be made based on the findings of this study as a crucial component of causality discussions in clinical research are different time points of measurement. Only longitudinal research can offer further evidence for a hypothesised relationship between high levels of health anxiety and psychological adjustment. The current study can only state that they are associated. Future research should attempt to investigate health anxiety and adjustment in a longitudinal sample. However, the model chosen in this study was based on theoretical underpinnings and careful consideration of existing research.

For example, there is a good evidence base for a relationship between self-efficacy and distress and maladjustment (Bandura, 1989; Bandura et al., 2003; Bandura et al., 1999). The construct also has been found to be of high importance in stoma adjustment (Simmons et al., 2007) and this stoma study supports this evidence by replicating the findings.

Health anxiety has been investigated in medical conditions and was found to be related to health-related quality of life (Escobar et al., 2013; Hassel et al., 2012; Jörngården et al., 2007; Park et al., 2014; Spiegel et al., 2011; van Esch et al., 2008). To our best knowledge, health anxiety was not yet examined in a post-stoma-surgery sample. It seems fair to say that a major advantage of the current study is the fact that adjustment was measured very specifically (i.e. adjustment to several aspect of living with a stoma) with a questionnaire developed for this patient group and which has excellent psychometric properties. Many studies examining psychological variables in cancer populations have used far broader constructs such as quality of life. More specific assessments can have the benefit of providing ideas for interventions and to tailor them to the specific needs of patients. Moreover, it informs the assessment by the clinical staff and what to look out for.

Another point to discuss in respect of the design of this study are variables the study could not control for. It would have been an advantage to collect data about the mental health of patients to control for pre-existing psychological problems that are likely to influence the adjustment process. Moreover, the proposed model in this study explained about 40% of the variance in stoma

adjustment, showing that about 60% of the variability in adjustment scores are associated to factors the model did not account for. Future studies should further explore risk and protective factors in this patient group.

Despite those limitations, this study has helped to understand the relationships between psychological variables such as health anxiety, self-efficacy, and adjustment in stoma patients. The association between high health anxiety and lower adjustment has important clinical implications, which are discussed below. These variables (i.e. health anxiety and self-efficacy) are modifiable and therefore of great clinical use. Moreover, this study has made attempts to not only understand risk factors that might impact adjustment but also considered protective factors and how they interact with the adjustment processes.

Generalisability

The conclusions of the findings are limited to a sample of patients undergoing stoma surgery. The underlying condition was measured in three broad categories: cancer, benign, and other diagnosis. It would have been an advantage to collect medical data in a more detailed manner, as it would have been interesting to investigate differences between patients based on their diagnosis and severity of symptoms and future studies should attempt to make such comparisons. Even with the information available in this study, group comparisons were not possible due to small cell size.

The sample had low variability in its demographic data. Patients were predominantly from the same county in the UK and they were all White British

apart from 1 patient. These factors impact on the generalisability as cross-cultural differences and diversity were not considered.

CONCLUSIONS AND CLINICAL IMPLICATIONS

Despite its limitations, the study has offered valuable insight into the adjustment processes in stoma patients. The study has made an attempt to explore health anxiety in the context of stoma surgery and has found that the disorder is highly prevalent and seems to impact on the adaptation of patients to living with a stoma.

Stoma care is one of the main factors influencing how patients adjust to living with their stoma (Baxter & Salter, 2000; Gray et al., 2006; Metcalf, 1999; White, 2010). The current study has revealed that patients are highly satisfied with their preparation for surgery and for living with the stoma by the stoma care team, yet many struggle to come to terms with the stoma and exhibit distress.

Health anxiety is indeed a helpful construct to consider in this regard as the theory and the model of the disorder suggest that patients may engage in coping behaviours that inadvertently prolong distressing feelings and psychological impairment. Highly health anxious patients may not be able to implement the skills taught by the nursing team and, therefore, not foster self-efficacy beliefs in respect of feeling able to cope with living with the stoma. Consequently, it could be argued that health anxious cognitions and behaviours hinder the adjustment process by preventing stoma self-efficacy from developing and growing. Thus, it is important to assess patients for such anxiety symptoms, as they may need to be treated first before patients can adaptively get used to their stoma and illness

prognosis. Once patients have no or reduced/managed clinical levels of health anxiety, they might be more likely, or more able, to engage in the helpful adjustment process of coming to terms with their stoma, learning skills necessary to take care of their stoma, and accepting their situation.

Needless to say, that similar argument also apply to other anxiety and depressive symptoms that are known to impact self-efficacy beliefs and thereby adaptation. However, health anxiety as a specific form of anxiety symptomatology is worthwhile to consider separately given the high prevalence rate in medical conditions and the explicit nature of safety seeking behaviours and their impact on the perpetuation of overall psychological impairment.

In addition to targeting illness and symptom response and perception (including the stoma) in interventions, the current research suggest that stoma patients may also benefit from interventions focusing on health anxiety and self-efficacy to be able to live well with their stoma.

For example, psycho-education about mental health problems and chronic medical conditions may help patients to make sense of their psychological symptoms and normalise difficulties that occur post stoma surgery. Patients may benefit from being taught general coping strategies in order to help them feel equipped (with helpful techniques) in times of high demand and stress. Emotional regulation strategies are of critical importance as patients will benefit from learning to deal with their high levels of anxiety without resorting to unhelpful coping strategies (i.e. safety seeking behaviours). Communication techniques, including how to talk about the stoma, might help to enhance social

self-efficacy as well as practical skills that can support patients in managing their stoma. The study has shown that patients may struggle to live well with their stoma if their suffer from clinical levels of health anxiety. Therefore, the assessment and treatment of health anxious cognitions, emotions, and the associated safety seeking behaviours may need to be a first step in helping patients to adjust to their stoma.

REFERENCES

Alberts, N. M., Sharpe, D., Kehler, M. D., & Hadjistavropoulos, H. D. (2011). Health anxiety: Comparison of the latent structure in medical and non-medical samples. *Journal of Anxiety Disorders, 25*(4), 612-614.

American Psychiatric Association, A. (2013). *Diagnostic and statistical manual for mental disorders.* (5th ed.). Washington: American Psychiatric Association.

American_Cancer_Society. (2015). Achieving 80% by 2018 Screening Goal Could Prevent 200,000 Colon Cancer Deaths in Less Than 2 Decades. Retrieved 15.04.2015, from http://www.cancer.org/cancer/news/news/impact-of-achieving-80-by-2018-screening-goal

Amri, R., Bordeianou, L. G., Sylla, P., & Berger, D. L. (2015). Colon cancer surgery following emergency presentation: effects on admission and stage-adjusted outcomes. *The American Journal of Surgery, 209*(2), 246-253.

Arntz, A., Rauner, M., & Van den Hout, M. (1995). "If I feel anxious, there must be danger": Ex-consequentia reasoning in inferring danger in anxiety disorders. *Behaviour Research and Therapy, 33*(8), 917-925.

Bandura, A. (1977). Self-efficacy - Towards a unifying theory of behavioural change. *Psychological Review, 84*(2), 191-215.

Bandura, A. (1982). Self-efficacy mechanism in human agency. *American Psychologist, 37*(2), 122-147.

Bandura, A. (1989). Regualtion of cognitive processes through perceived self-efficacy. *Developmental Psychology, 25*(5), 729-735.

Bandura, A. (1992). Exercise of personal agency through the self-efficacy mechanism. In R. Schwarzer (Ed.), *Self-efficacy: Thought control of action*. New York: Taylor & Francis.

Bandura, A. (1997). *Self-efficacy: The exercise of control*. New York: W H Freeman / Times Books / Henry Holt & Co; US.

Bandura, A., Caprara, G. V., Barbaranelli, C., Gerbino, M., & Pastorelli, C. (2003). Role of affective self-regulatory efficacy in diverse spheres of psychosocial functioning. *Child Development, 74*(3), 769-782.

Bandura, A., Pastorelli, C., Barbaranelli, C., & Caprara, G. V. (1999). Self-efficacy pathways to childhood depression. *Journal of Personality and Social Psychology, 76*(2), 258-269.

Baron, R. M., & Kenny, D. A. (1986). The moderator-mediator variable distinction in social psychological research: Conceptual, strategic, and statistical considerations. *Journal of Personality and Social Psychology, 51*(6), 1173-1182.

Barrett, B., Tyrer, P., Tyrer, H., Cooper, S., Crawford, M. J., & Byford, S. (2012). An examination of the factors that influence costs in medical patients with health anxiety. *Journal of Psychosomatic Research, 73*(1), 59-62.

Baxter, A., & Salter, M. (2000). Stoma care nursing. *Nursing Standard Royal College of Nursing, 14*(19).

Bekkers, M. J. T. M., van Knippenberg, F. C. E., van den Borne, H. W., & van Berge Henegouwen, G. P. (1996). Prospective evaluation of psychosocial adaptation to stoma surgery: The role of self-efficacy. *Psychosomatic Medicine, 58*(2), 183-191.

Bekkers, M. J. T. M., van Knippenberg, F. C. E., van Dulmen, A. M., van den Borne, H. W., & van Berge Henegouwen, G. P. (1997). Survival and psychosocial adjustment to stoma surgery and nonstoma bowel resection: A 4-year follow-up. *Journal of Psychosomatic Research, 42*(3), 235-244.

Bekkers, M. J. T. M., Vandenborne, H. W., Bergsma, J., Poen, H., & Vanbergehenegouwen, G. P. (1993). Psychosocial adjustment to stoma surgery and non-stoma bowel resection - A prospective study. *Gastroenterology, 104*(4).

Brown, H., & Randle, J. (2005). Living with a stoma: a review of the literature. *Journal of Clinical Nursing, 14*(1), 74-81.

CancerResearchUK. (2014). About bowl cancer. Retrieved 30.05. 2014, from http://www.cancerresearchuk.org

Chilcot, J., & Moss-Morris, R. (2013). Changes in illness-related cognitions rather than distress mediate improvements in irritable bowel syndrome (IBS) symptoms and disability following a brief cognitive behavioural therapy intervention. *Behaviour Research and Therapy, 51*(10), 690-695.

Clark, D. M. (1999). Anxiety disorders: why they persist and how to treat them. *Behaviour Research and Therapy, 37, Supplement 1*, 5-27.

Clark, D. M., Salkovskis, P. M., Hackmann, A., Wells, A., Fennell, M., Ludgate, J., . . . Gelder, M. (1998). Two psychological treatments for hypochondriasis - A randomised controlled trial. *British Journal of Psychiatry, 173*, 218-225.

Clark-Carter, D. (2010). *Quantitative Psychological Research* (3rd ed.): Psychology Press.

Dekker, J. W. T., Gooiker, G. A., Bastiaannet, E., van den Broek, C. B. M., van der Geest, L. G. M., van de Velde, C. J., . . . Liefers, G. J. (2014). Cause of death the first year after curative colorectal cancer surgery; a prolonged impact of the surgery in elderly colorectal cancer patients. *European Journal of Surgical Oncology, 40*(11), 1481-1487.

Dempster, M., McCorry, N. K., Brennan, E., Donnelly, M., Murray, L. J., & Johnston, B. T. (2011). Illness perceptions among carer–survivor dyads are related to psychological distress among Oesophageal cancer survivors. *Journal of Psychosomatic Research, 70*(5), 432-439.

Dennison, L., Moss-Morris, R., & Chalder, T. (2009). A review of psychological correlates of adjustment in patients with multiple sclerosis. *Clinical Psychology Review, 29*(2), 141-153.

Ernstmann, N., Neumann, M., Ommen, O., Galushko, M., Wirtz, M., Voltz, R., . . . Pfaff, H. (2009). Determinants and implications of cancer patients' psychosocial needs. *Supportive Care in Cancer, 17*(11), 1417-1423.

Escobar, A., Billbao, A., Trancho, Z., Quintana, J., Sarasqueta, C., & Baré, M. (2013). Influence of Anxiety and Depression on 1-Year Health Related Quality of Life in Colorectal Cancer Patients. *Value in Health, 16*(7), 421-422.

Fairchild, A. J., Mackinnon, D. P., Taborga, M. P., & Taylor, A. B. (2009). R2 effect-size measures for mediation analysis. . *Behaviour Research Methods, 41*, 486-498.

Field, A. (2009). *Discovering statistics using SPSS* (3rd ed.). London: SAGE Publications.

Foulis, W., & Mayberry, J. F. (1990). Elderly ileostomists and their social problems. *Journal of Clinical Gastroenterology, 12*(3), 276-278.

Frazier, P. A., Tix, A. P., & Barron, K. E. (2004). Testing moderator and mediator effects in counseling psychology research. *Journal of Counseling Psychology, 51*(1), 115-134.

Gavaruzzi, T., Giandomenico, F., Del Bianco, P., Lotto, L., Perin, A., & Pucciarelli, S. (2014). Quality of life after surgery for rectal cancer. *Recent Results in Cancer Research., 203*, 117-149.

Giese-Davis, J., Hermanson, K., Koopman, C., Weibel, D., & Spiegel, D. (2000). Quality of couples' relationship and adjustment to metastatic breast cancer. *Journal of Family Psychology, 14*(2), 251-266.

Graça P., M., Figueiredo, A. P., & Fincham, F. D. (2012). Anxiety, depression, traumatic stress and quality of life in colorectal cancer after different

treatments: A study with Portuguese patients and their partners. *European Journal of Oncology Nursing, 16*(3), 227-232.

Gray, E. H., Blackinton, J., & White, G. M. (2006). Stoma care in the school setting. *The Journal of school nursing : the official publication of the National Association of School Nurses, 22*(2), 74-80.

Hasenbring, M. I., Kreddig, N., Deges, G., Epplen, J. T., Kunstmann, E., Stemmler, S., . . . Schmiegel, W. (2011). Psychological Impact of Genetic Counseling for Hereditary Nonpolyposis Colorectal Cancer: The Role of Cancer History, Gender, Age, and Psychological Distress. *Genetic Testing and Molecular Biomarkers, 15*(4), 219-225.

Hassel, A. J., Danner, D., Freier, K., Hofele, C., Becker-Bikowski, K., & Engel, M. (2012). Oral health-related quality of life and depression/anxiety in long-term recurrence-free patients after treatment for advanced oral squamous cell cancer. *Journal of Cranio-Maxillofacial Surgery, 40*(4), 99-102.

Herkommer, K., Hahn, A., Dinkel, A., Marten-Mittag, B., Herschbach, P., & Gschwend, J. (2012). Fear of progression among long-term prostate cancer patients illness perceptions and family history as potential predictors. . *The Journal of Urology, 187*(4, Supplement), 455.

Hyphantis, T., Paika, V., Almyroudi, A., Kampletsas, E. O., & Pavlidis, N. (2011). Personality variables as predictors of early non-metastatic colorectal cancer patients' psychological distress and health-related quality of life: A

one-year prospective study. *Journal of Psychosomatic Research, 70*(5), 411-421.

IARC_GLOBOCAN. (2012). Colorectal Cancer: Estimated Incidence, Mortality and Prevalence Worldwide in 2012. Retrieved 25.04.2015, from http://globocan.iarc.fr/Pages/fact_sheets_cancer.aspx

Janzen Claude, J. A., Hadjistavropoulos, H. D., & Friesen, L. (2014). Exploration of health anxiety among individuals with diabetes: Prevalence and implications. *Journal of Health Psychology, 19*(2), 312-322.

Jenks, J. M., Morin, K. H., & Tomaselli, N. (1997). The influence of ostomy surgery on body image in patients with cancer. *Applied Nursing Research, 10*(4), 174-180.

Jopson, N. M., & Moss-Morris, R. (2003). The role of illness severity and illness representations in adjusting to multiple sclerosis. *Journal of Psychosomatic Research, 54*(6), 503-511.

Jörngården, A., Mattsson, E., & von Essen, L. (2007). Health-related quality of life, anxiety and depression among adolescents and young adults with cancer: A prospective longitudinal study. *European Journal of Cancer, 43*(13), 1952-1958.

Kehler, M. D., & Hadjistavropoulos, H. D. (2009). Is health anxiety a significant problem for individuals with multiple sclerosis? *Journal of behavioral medicine, 32*(2), 150-161.

Kement, M., Gezen, C., Aydin, H., Haksal, M., Can, U., Aksakal, N., & Oncel, M. (2014). A Descriptive Survey Study to Evaluate the Relationship Between Socio-demographic Factors and Quality of Life in Patients with a Permanent Colostomy. *Ostomy Wound Management, 60*(10), 18-23.

Kenig, J., & Richter, P. (2013). Emergency and elective surgery in elderly patients with colorectal cancer. *Journal of Geriatric Oncology, 4, Supplement 1*(0).

Kenig, J., Zychiewicz, B., Olszewska, U., & Richter, P. (2015). Screening for frailty among older patients with cancer that qualify for abdominal surgery. *Journal of Geriatric Oncology, 6*(1), 52-59.

Klein, D. C., Fencilmorse, E., & Seligman, M. E. P. (1976). Learned helplessness, depression, and attribution of failure. *Journal of Personality and Social Psychology, 33*(5), 508-516.

Knowles, S. R., Wilson, J., Wilkinson, A., Connell, W., Salzberg, M., Castle, D., . . . Kamm, M. A. (2013). Psychological Well-Being and Quality of Life in Crohn's Disease Patients With an Ostomy A Preliminary Investigation. *Journal of Wound Ostomy and Continence Nursing, 40*(6), 623-629.

Knudsen, A. K., Berge, L. I., Skogen, J. C., Veddegjærde, K.-E., & Wilhelmsen, I. The prospective association between health anxiety and cancer detection: A cohort study linking the Hordaland Health Study (HUSK) with the Norwegian Cancer Registry. *Journal of Psychosomatic Research*.

Lazarus, R. S. (2000). Toward better research on stress and coping. *American Psychologist, 55*(6), 665-673.

Lazarus, R. S. (2006). Emotions and interpersonal relationships: Toward a person-centered conceptualization of emotions and coping. *Journal of Personality, 74*(1), 9-46.

Lazarus, R. S., & Folkman, S. (1984). *Stress, appraisal and coping.* New York: Springer.

LeBouthillier, D. M., Thibodeau, M. A., Alberts, N. M., Hadjistavropoulos, H. D., & Asmundson, G. J. G. (2015). Do people with and without medical conditions respond similarly to the Short Health Anxiety Inventory? An assessment of differential item functioning using item response theory. *Journal of Psychosomatic Research, 78*(4), 384-390.

Leonhart, R., Fischer, I., Koch, H., Tang, L., Pang, Y., Schäfert, R., & Fritzsche, K. (2015). Connections between physical symptom severity, health anxieties, perception of the disease, emotional stress and quality of life in one sample of Chinese breast cancer patients. *Journal of Psychosomatic Research, 78*(6), 609.

Liao, C., & Qin, Y. (2014). Factors associated with stoma quality of life among stoma patients. *International Journal of Nursing Sciences, 1*(2), 196-201.

Merluzzi, T. V., Philip, E. J., Vachon, D. O., & Heitzmann, C. A. (2011). Assessment of self-efficacy for caregiving: the critical role of self-care in caregiver stress and burden. *Palliative & supportive care, 9*(1), 15-24.

Metcalf, C. (1999). Stoma care: empowering patients through teaching practical skills. *British Journal of Nursing, 8*(9), 593-600.

Miles, A., & Wardle, J. (2006). Adverse psychological outcomes in colorectal cancer screening: Does health anxiety play a role? *Behaviour Research and Therapy, 44*(8), 1117-1127.

Millar, K., Purushotham, A. D., McLatchie, E., George, W. D., & Murray, G. D. (2005). A 1-year prospective study of individual variation in distress, and illness perceptions, after treatment for breast cancer. *Journal of Psychosomatic Research, 58*(4), 335-342.

Miller, W. R., & Seligman, M. E. P. (1975). Depression and learned helplessness in man. *Journal of Abnormal Psychology, 84*(3), 228-238.

Mols, F., Denollet, J., Kaptein, A. A., Reemst, P. H. M., & Thong, M. S. Y. (2012). The association between Type D personality and illness perceptions in colorectal cancer survivors: A study from the population-based PROFILES registry. *Journal of Psychosomatic Research, 73*(3), 232-239.

Mrak, K., Jagoditsch, M., Eberl, T., Klingler, A., & Tschmelitsch, J. (2011). Long-term quality of life in pouch patients compared with stoma patients following rectal cancer surgery. *Colorectal Disease, 13*(12), 403-410.

Nausheen, B., Gidron, Y., Peveler, R. C., & Moss-Morris, R. (2009). Social support and cancer progression: A systematic review. *Journal of Psychosomatic Research, 67*(5), 403-415.

Nordstrom, G. M., & Nyman, C. R. (1991). Living with a urostomy. A follow up with special regard to the peristomal-skin complications, psychosocial

and sexual life. *Scandinavian journal of urology and nephrology. Supplementum, 138*, 247-251.

Nugent, K. P., Daniels, P., Stewart, B., Patankar, R., & Johnson, C. D. (1999). Quality of life in stoma patients. *Diseases of the Colon & Rectum, 42*(12), 1569-1574.

Orsini, R. G., Thong, M. S. Y., van de Poll-Franse, L. V., Slooter, G. D., Nieuwenhuijzen, G. A. P., Rutten, H. J. T., & de Hingh, I. H. J. T. (2013). Quality of life of older rectal cancer patients is not impaired by a permanent stoma. *European Journal of Surgical Oncology (EJSO), 39*(2), 164-170.

Oxford Dictionary of English. (2010). Oxford University Press.

Park, C., Kim, G., Jiang, S., & Lawson, K. A. (2014). The Association of Comorbid Anxiety and Mood Disorders with Health-Related Quality of Life Among Cancer Survivors. *Value in Health, 17*(3).

Paterson, C., Robertson, A., & Nabi, G. (2015). Exploring prostate cancer survivors' self-management behaviours and examining the mechanism effect that links coping and social support to health-related quality of life, anxiety and depression: A prospective longitudinal study. *European Journal of Oncology Nursing, 19*(2), 120-128.

Persson, E., & Hellström, A.-L. (2002). Experiences of Swedish men and women 6 to 12 weeks after ostomy surgery. *Journal of WOCN, 29*(2), 103-108.

Preacher, K. J., & Hayes, A. F. (2008). Asymptotic and resampling strategies for assessing and comparing indirect effects in multiple mediator models. *Behavior Research Methods, 40*, 879-891.

Price, A., Goodwin, L., Rayner, L., Shaw, E., Hansford, P., Sykes, N., . . . Lee, W. (2012). Illness Perceptions, Adjustment to Illness, and Depression in a Palliative Care Population. *Journal of pain and symptom management, 43*(5), 819-832.

Rachman, S. (1998). Progress toward a cognitive clinical psychology. *Journal of Psychosomatic Research, 45*(5), 387-389.

Ristvedt, S. L., & Trinkaus, K. M. (2009). Trait anxiety as an independent predictor of poor health-related quality of life and post-traumatic stress symptoms in rectal cancer. *British Journal of Health Psychology, 14*, 701-715.

Rode, S., Salkovskis, P., Dowd, H., & Hanna, M. (2006). Health anxiety levels in chronic pain clinic attenders. *Journal of Psychosomatic Research, 60*(2), 155-161.

Sales, P. M. G., Carvalho, A. F., McIntyre, R. S., Pavlidis, N., & Hyphantis, T. N. (2014). Psychosocial predictors of health outcomes in colorectal cancer: A comprehensive review. *Cancer Treatment Reviews, 40*(6), 800-809.

Salkovskis, P. M. (1996a). *The cognitive approach to anxiety: Threat beliefs, safety-seeking behavior, and the special case of health anxiety and obsessions*.

Salkovskis, P. M. (1996c). *The cognitive approach to anxiety: Threat beliefs, safety-seeking behavior, and the special case of health anxiety and obsessions.* New York: Guilford Press.

Salkovskis, P. M., Rimes, K. A., Warwick, H. M. C., & Clark, D. M. (2002). The Health Anxiety Inventory: development and validation of scales for the measurement of health anxiety and hypochondriasis. *Psychological Medicine, 32*(5), 843-853.

Salkovskis, P. M., & Warwick, H. M. C. (1986). Morbid preoccupations, health anxiety and reasssurance - A cognitive behavioral approach to hypochondriasis. *Behaviour Research and Therapy, 24*(5), 597-602.

Salkovskis, P. M., Wroe, A. L., & Rees, M. C. P. (2004). Shared decision-making, health choices and the menopause. *The journal of the British Menopause Society, 10 Suppl 1*, 13-17.

Salles, V. J. A., Becker, C. P. P., & Faria, G. M. R. (2014). The influence of time on the quality of life of patients with intestinal stoma. *Journal of Coloproctology, 34*(2), 73-75.

Salomé, G. M., de Almeida, S. A., & Silveira, M. M. (2014). Quality of life and self-esteem of patients with intestinal stoma. *Journal of Coloproctology, 34*(4), 231-239.

Salter, M. J. (1992a). Aspects of sexuality for patients with stomas and continent pouches. *Journal of ET nursing : official publication, International Association for Enterostomal Therapy, 19*(4), 126-130.

Salter, M. J. (1992d). What are the differences in body-image between patients with a conventional stoma compared with those who have had a convential stoma followed by a continent pouch. *Journal of Advanced Nursing, 17*(7), 841-848.

Salter, M. J. (1997). *Altered body image: The nurse's role.* London: Bailiere Tindall.

Santos, A. C., Martins, L. L. T., Brasil, A. M. S., Pinto, S. A., Neto, S. G., & de Oliveira, E. C. (2014). Emergency surgery for complicated colorectal cancer in central Brazil. *Journal of Coloproctology, 34*(2), 104-108.

Saunders, R. N., & Hemingway, D. (2008). Intestinal stomas. *Surgery (Oxford), 26*(8), 347-351.

Seligman, M. E. (1972). Learned helplessness. *Annual Review of Medicine, 23*(5).

Sharpe, L., Patel, D., & Clarke, S. (2011). The relationship between body image disturbance and distress in colorectal cancer patients with and without stomas. *Journal of Psychosomatic Research, 70*(5), 395-402.

Simmonds, P. D., Best, L., George, S., Baughan, C., Buchanan, R., Davis, C., . . . Williams, C. (2000). Surgery for colorectal cancer in elderly patients: a systematic review. *The Lancet, 356*(9234), 968-974.

Simmons, K. L., Smith, J. A., Bobb, K.-A., & Liles, L. L. M. (2007). Adjustment to colostomy: stoma acceptance, stoma care self-efficacy and interpersonal relationships. *Journal of Advanced Nursing, 60*(6), 627-635.

Simmons, K. L., Smith, J. A., & Maekawa, A. (2009). Development and Psychometric Evaluation of the Ostomy Adjustment Inventory-23. *Journal of Wound Ostomy and Continence Nursing, 36*(1), 69-76.

Simon, A. E., Steptoe, A., & Wardle, J. (2005). Socioeconomic status differences in coping with a stressful medical procedure. *Psychosomatic Medicine, 67*(2), 270-276.

Spiegel, T., Gerharz, E. W., Müller, J. G., Riedmiller, H., & Faller, H. (2011). Health-related quality of life, anxiety and depression in long-term survivors of testicular germ cell cancer. *European Urology Supplements, 10*(2), 321.

Sprangers, M. A. G., Taal, B. G., Aaronson, N. K., & Tevelde, A. (1995). Quality-of-life in colorectal cancer - Stoma versus nonstoma patients. *Diseases of the Colon & Rectum, 38*(4), 361-369.

SPSS, Inc., S., Chicago, IL, & USA.

Tang, N. K. Y., Salkovskis, P. M., Poplavskaya, E., Wright, K. J., Hanna, M., & Hester, J. (2007). Increased use of safety-seeking behaviors in chronic back pain patients with high health anxiety. *Behaviour Research and Therapy, 45*(12), 2821-2835.

Taylor, C., & Morgan, L. (2011). Quality of life following reversal of temporary stoma after rectal cancer treatment. *European Journal of Oncology Nursing, 15*(1), 59-66.

Tejido-Sanchez, A., Garcia-Gonzalez, L., Jimenez-Alcaide, E., Arrebola-Pajares, A., Medina-Polo, J., Villacampa-Auba, F., & Diaz-Gonzalez, R. (2014). Quality of Life in Patients with ileal Conduit Cystectomy Due to Bladder Cancer. *Actas Urologicas Espanolas, 38*(2), 90-95.

Thomas, C., Madden, F., & Jehu, D. (1987a). Psychological effects of stomas: 1. Psychosocial morbidity one year after surgery. *Journal of Psychosomatic Research, 31*(3), 311-316.

Thomas, C., Madden, F., & Jehu, D. (1987c). Psychological effects of stomas: 2. Factors influencing outcome. *Journal of Psychosomatic Research, 31*(3), 317-323.

Thomas, C., Turner, P., & Madden, F. (1988). Coping and the outcome of stoma surgery. *Journal of Psychosomatic Research, 32*(4-5), 457-467.

Traeger, L., Penedo, F. J., Gonzalez, J. S., Dahn, J. R., Lechner, S. C., Schneiderman, N., & Antoni, M. H. (2009). Illness perceptions and emotional well-being in men treated for localized prostate cancer. *Journal of Psychosomatic Research, 67*(5), 389-397.

Tyrer, P., Cooper, S., Crawford, M., Dupont, S., Green, J., Murphy, D., . . . Tyrer, H. (2011). Prevalence of health anxiety problems in medical clinics. *Journal of Psychosomatic Research, 71*(6), 392-394.

van der Have, M., Minderhoud, I. M., Kaptein, A. A., Leenders, M., Siersema, P. D., Fidder, H. H., & Oldenburg, B. (2013). Substantial impact of illness

perceptions on quality of life in patients with Crohn's disease. *Journal of Crohn's and Colitis, 7*(8), 292-301.

van Esch, L., de Vries, J., van der Steeg, A. F. W., & Roukema, J. A. (2008). Health status in breast cancer patients is influenced by trait anxiety and type of operation. *European Journal of Cancer Supplements, 6*(7), 92.

Vironen, J. H., Kairaluoma, M., Aalto, A.-M., & Kellokumpu, I. H. (2006). Impact of functional results on quality of life after rectal cancer surgery. *Diseases of the Colon & Rectum, 49*(5), 568-578.

Warwick, H. M. C., & Salkovskis, P. M. (1989). Cognitive and behavioral characteristics of primary hypochaondriasis. . *Scandinavian Journal of Behaviour Therapy, 18*(2), 85-92.

Warwick, H. M. C., & Salkovskis, P. M. (1990). Hypochondriasis. . *Behaviour Research and Therapy, 28*(2), 105-117.

Wells, A., & Carter, K. (1999). Preliminary tests of a cognitive model of generalized anxiety disorder. *Behaviour Research and Therapy, 37*(6), 585-594.

Wells, A., & Carter, K. (2001). Further tests of a cognitive model of generalized anxiety disorder: Metacognitions and worry in GAD, panic disorder, social phobia, depression, and nonpatients. *Behavior Therapy, 32*(1), 85-102.

Wells, A., & Papageorgiou, C. (1998). Relationships between worry, obsessive–compulsive symptoms and meta-cognitive beliefs. *Behaviour Research and Therapy, 36*(9), 899-913.

Wells, A., Welford, M., King, P., Papageorgiou, C., Wisely, J., & Mendel, E. (2010). A pilot randomized trial of metacognitive therapy vs applied relaxation in the treatment of adults with generalized anxiety disorder. *Behaviour Research and Therapy, 48*(5), 429-434.

White, C. A. (1998). Psychological management of stoma-related concerns. *Nursing Standard Royal College of Nursing, 12*(36), 35-38.

White, C. A. (2010). *Living with a stoma*. London: Sheldon Press.

White, C. A., & Unwin, J. C. (1998). Post-operative adjustment to surgery resulting in the formation of a stoma: The importance of stoma-related cognitions. *British Journal of Health Psychology, 3*, 85-93.

Worster, B., & Holmes, S. (2008). The preoperative experience of patients undergoing surgery for colorectal cancer: A phenomenological study. *European Journal of Oncology Nursing, 12*(5), 418-424.

Wroe, A. L., & Thomas, M. G. (2003). Intentional and unintentional nonadherence in patients prescribed HAART treatment regimens. *Psychology, health & medicine, 8*(4), 453-463.

Zhang, M., Chan, S. W., You, L., Wen, Y., Peng, L., Liu, W., & Zheng, M. (2014). The effectiveness of a self-efficacy-enhancing intervention for Chinese patients

with colorectal cancer: A randomized controlled trial with 6-month follow up. *International journal of nursing studies, 51*(8), 1083-1092.

Zhang, M., Zheng, M., Liu, W., Wen, Y., Wu, X., & Liu, Q. (2015). The influence of demographics, psychological factors and self-efficacy on symptom distress in colorectal cancer patients undergoing post-surgical adjuvant chemotherapy. *European Journal of Oncology Nursing, 19*(1), 89-96.

Zheng, M., Zhang, J., Qin, H., Fang, Y., & Wu, X. (2013). Telephone follow-up for patients returning home with colostomies: Views and experiences of patients and enterostomal nurses. *European Journal of Oncology Nursing, 17*(2), 184-189.

APPENDIX

APPENDIX 1 R&D APPROVAL LETTER NHS RECRUITMENT SITE

Ashford and St. Peter's Hospitals NHS
NHS Foundation Trust

Office of Research & Development

St Peter's Hospital
Guild ford Road
Chertsey
Surrey
KT16 0PZ
Tel: 0193-272-3534
Fax: 0193-272-3395

26th March 2013

Dear Ms Simone Raenker

RE: R&D Conditional Approval- 'Investigating the relationship between health anxiety and psychological adjustment in patients undergoing stoma surgery'

Thank you very much for presenting your research proposal to the Trust R&D Committee on Thursday 21st March 2013. I am very glad to inform you that the Committee has given conditional approval to your study subject to **Ethics favourable opinion from the National Research Ethics Service (NRES).**

After obtaining Ethics Approval, please email me the electronic copies of all the Ethics approved documents at freda.gomes@asph.nhs.uk . After receiving the documents, R&D office will issue you a formal R&D approval letter. However, if you need any more information, please do not hesitate to contact me.

I look forward to receiving the Ethics favorable opinion and related documents in due course.

Best wishes

Yours sincerely,

Miss Freda Gomes
Research Governance Officer
E-Mail: Freda.Gomes@asph.nhs.uk

Copy to: Dr Isaac John, ASPH
Dr Martha Wrigley, ASPH
Dr Abigail Wroe, Royal Holloway University of London

APPENDIX 2 NRES ETHICS FAVOURABLE OPINION AND STUDY APPROVAL LETTER

NHS
Health Research Authority
NRES Committee North West - Greater Manchester South
3rd Floor, Barlow House
4 Minshull Street
Manchester
M1 3DZ

Telephone: 0161 625 7830

21 October 2014

Dr. Simone Raenker
Trainee Clinical Psychologist
Camden and Islington Foundation Trust
Department of Psychology, Doctorate in Clinical Psychology
Royal Holloway, University of London
Egham, Surrey
TW20 0EX

Dear Dr Raenker,

Study title:	**The association between health anxiety and psychological adjustment in patients undergoing stoma surgery.**
REC reference:	**14/NW/1286**
Protocol number:	**n/a**
IRAS project ID:	**124924**

Thank you for your further e-submissions on the 17th and 20th October, responding to the Proportionate Review Sub-Committee's request for changes to the documentation for the above study.

The revised documentation has been reviewed and approved by the sub-committee.

We plan to publish your research summary wording for the above study on the NRES website, together with your contact details, unless you expressly withhold permission to do so. Publication will be no earlier than three months from the date of this favourable opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to withhold permission to publish, please contact the REC Manager Nicola Burgess, nrescommittee.northwest-gmsouth@nhs.net.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations.

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to contest the need for registration they should contact Catherine Blewett (catherineblewett@nhs.net), the HRA does not, however, expect exceptions to be made. Guidance on where to register is provided within IRAS.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study.

Approved documents

The documents reviewed and approved by the Committee are:

Document	*Version*	*Date*
Copies of advertisement materials for research participants [Advert]	3	16 October 2014
Copies of advertisement materials for research participants [Recruitment form - short study info and participant contact details]	1	05 September 2014
Covering letter on headed paper [Cover letter]	1	27 June 2014
Covering letter on headed paper [Response letter to REC provisional opinion letter]	1	16 October 2014
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Indemnity letter]		
IRAS Checklist XML [Checklist_20102014]		20 October 2014
Letters of invitation to participant [Invitations to take part]	1	05 September 2014
Other [Information about psych support for participants]	1	27 June 2014
Other [Email containing further information requested]		
Participant consent form [Info sheet and consent form]	2	16 October 2014
Participant consent form [information sheet and consent form]	2	16 October 2014
Participant information sheet (PIS) [Info sheet and consent form]	2	16 October 2014
Participant information sheet (PIS) [information sheet and consent form]	2	16 October 2014
REC Application Form [REC_Form_05092014]		05 September 2014
Research protocol or project proposal [Protocol]	5	16 October 2014
Response to Request for Further Information		
Summary CV for Chief Investigator (CI)	1	28 May 2014
Summary CV for supervisor (student research)	1	28 May 2014
Validated questionnaire [Post quest]	1	27 June 2014
Validated questionnaire [Baseline quest long. sample]	2	16 October 2014
Validated questionnaire [Quest for cross-sectional sample]	2	16 October 2014
Validated questionnaire [Follow up quest]	1	27 June 2014
Validated questionnaire [Quest cross-sec sample]	2	16 October 2014
Validated questionnaire [Pre-op questionnaire longitudinal sample]	2	16 October 2014

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:
http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

14/NW/1286	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project.

Yours sincerely

PP:
Professor Sobhan Vinjamuri
Chair

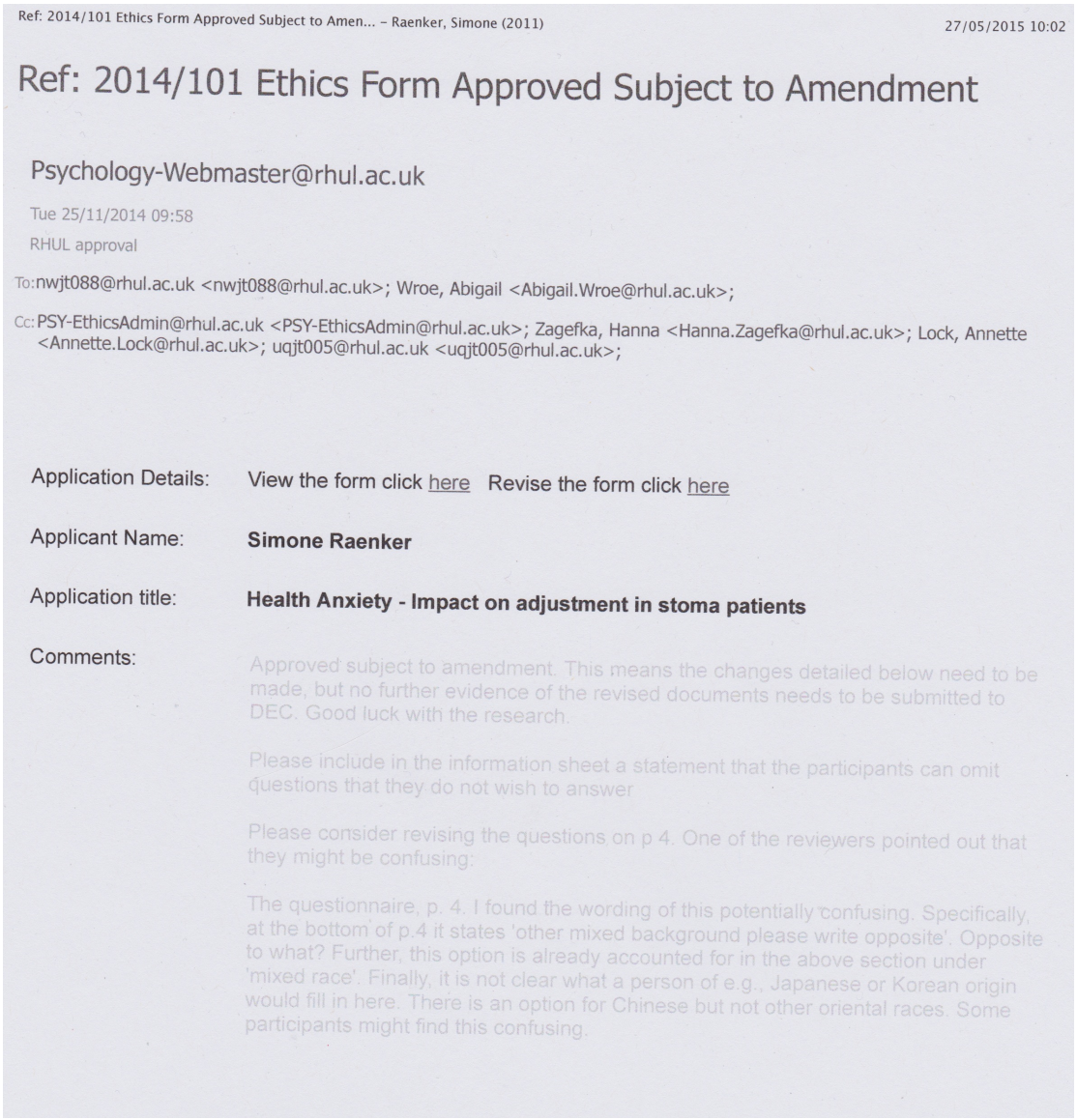
Email: nrescommittee.northwest-gmsouth@nhs.net

Enclosures: *"After ethical review – guidance for researchers"*

Copy to: *Dr. Abigail Wroe*

Miss Freda Gomes, Ashford and St. Peter's Hospital

APPENDIX 3 RHUL APPROVAL



Ref: 2014/101 Ethics Form Approved Subject to Amen... - Raenker, Simone (2011) 27/05/2015 10:02

Ref: 2014/101 Ethics Form Approved Subject to Amendment

Psychology-Webmaster@rhul.ac.uk

Tue 25/11/2014 09:58

RHUL approval

To: nwjt088@rhul.ac.uk <nwjt088@rhul.ac.uk>; Wroe, Abigail <Abigail.Wroe@rhul.ac.uk>;

Cc: PSY-EthicsAdmin@rhul.ac.uk <PSY-EthicsAdmin@rhul.ac.uk>; Zagefka, Hanna <Hanna.Zagefka@rhul.ac.uk>; Lock, Annette <Annette.Lock@rhul.ac.uk>; uqjt005@rhul.ac.uk <uqjt005@rhul.ac.uk>;

Application Details:	View the form click here Revise the form click here
Applicant Name:	**Simone Raenker**
Application title:	**Health Anxiety - Impact on adjustment in stoma patients**
Comments:	Approved subject to amendment. This means the changes detailed below need to be made, but no further evidence of the revised documents needs to be submitted to DEC. Good luck with the research. Please include in the information sheet a statement that the participants can omit questions that they do not wish to answer Please consider revising the questions on p 4. One of the reviewers pointed out that they might be confusing: The questionnaire, p. 4. I found the wording of this potentially confusing. Specifically, at the bottom of p.4 it states 'other mixed background please write opposite'. Opposite to what? Further, this option is already accounted for in the above section under 'mixed race'. Finally, it is not clear what a person of e.g., Japanese or Korean origin would fill in here. There is an option for Chinese but not other oriental races. Some participants might find this confusing.

APPENDIX 4 RECRUITMENT ADVERT

Ashford and St. Peter's Hospitals NHS
NHS Foundation Trust

Looking for participants for STOMA STUDY

St. Peter's Hospital Ashford and Royal Holloway, University of London are conducting a piece of research inviting patients, who have undergone stoma surgery, to participants in a study aimed to understand the experience of patients and how healthcare professionals can best support them.

This study aims to increase the understanding of what it means to patients to go through an operation that may result in a stoma. The results of this study will be used to inform clinical practice. For example, we hope to conclude from the research findings how patients can be supported before and after their surgery by the clinical team in order to address their needs and foster well-being and reduce stress.

The National Research Ethic Service and the Royal Holloway University of London ethic committee have approved this study. Data are treated anonymously (i.e. participants will receive a unique code) and patients can withdraw from taking part in this research project at any given point.

Anyone (18+ years old), who had stoma surgery in the past 6 months, is invited to take part.

Participation will involve the completion of a questionnaire, which will take approximately 30 minutes. You will be reimbursed with £5 once the assessment is completed.

Please contact me by sending a private message if you have seen this advert on social media, or email me on simone.raenker.2011@live.rhul.ac.uk or call +44 1784 443851 if you are interested in taking part. I look forward to hearing from you.

Many thanks and all the best,

Simone Raenker

NRES ethic approval no.: 14/NW/1286 Version 3 16/10/2014

APPENDIX 5 COVER LETTER TO RETROSPECTIVE SAMPLE

Ashford and St. Peter's Hospitals NHS
NHS Foundation Trust

Stoma Care Department
St Peter's Hospital
Guildford Road
Chertsey
Surrey
KT16 0PZ

DX 119775, Chertsey2

Tel 01932 722636
Webwww.ashfordstpeters.nhs.uk
Text Relayprefix numbers with 18001

Wednesday, 27 May 2015

Dear Sir / Madam,

We are inviting you to take part in a study we are currently running in which we are looking at ways how we can improve our service to patients with stoma. In order to do this, the stoma service and the research team are working closely together to carry out a study on people's perception of their health and illness.

We would be very grateful if you could consider taking part in this project.

We are interested in finding out how our patients have managed after undergoing stoma surgery. Therefore, we are contacting everyone, who had the operation within the last 12 months at St Peter's Hospital and ask whether they would be willing to complete a one-off questionnaire with Dr. Simone Raenker, who is a trainee clinical psychologist and helps with the research.

With this letter, you have received the contact detail form, study information sheet, consent form, questionnaire.

- Please read the information sheet carefully and feel free to ask Simone any questions.
- If you decide to take part, please ***complete and sign the enclosed consent form***. Please ***return the consent form*** in the stamped and addressed envelope.
- Please also ***complete the contact form*** (on the consent form) and ***send it back*** using the the stamped and addressed envelope
- We have also enclosed the ***questionnaire***. You can either ***complete the questionnaire on your own and send it back with the consent form***. Alternatively, you can ***go through the questions with Simone*** on the phone. Please feel free to let us know what would be your preferred option who feel most comfortable with.

The information you give us in the questionnaire will be looked at only by the research team involved in this project unless you wish to raise something with the stoma team. Your care will not be affected in any way. Your data will be stored securely and all data will be anonymised (i.e. each person is given a unique code and all identifyable information is removed). Any written report or presentation of the findings will not include identifiable information of those who took part. If you would like a summary of the findings, please tick the box on the consent form and we will send you a summary at the end of the resarch.

If you have any questions, please do not hesitate to contact your stoma nurse.

Thank you very much for your time reading this and for considering your participation. We would be hugely greatful if you could decide to take part help improving stoma care for patients.

With best wishes,

Stoma Nurse Team & Psychology Service

APPENDIX 6 COVER LETTER TO PROSPECTIVE SAMPLE

Ashford and St. Peter's Hospitals NHS
NHS Foundation Trust

Stoma Care Department
St Peter's Hospital
Guildford Road
Chertsey
Surrey
KT16 0PZ

DX 119775, Chertsey 2

Tel 01932 722636
Web www.ashfordstpeters.nhs.uk
Text Relay prefix numbers with 18001

Wednesday, 29 October 2014

Dear Sir / Madam,

We are inviting you to take part in a study we are currently running in which we are looking at ways how we can improve our service to patients with stoma. In order to do this, the stoma service and the psychology service are working closely together to carry out an audit of people's perception of their health and illness.

We would be very grateful if you could consider taking part in this project.

Your stoma nurse will be able to tell you more about the study and will help to make contact with the research team. Taking part in this project will involve the completion of questionnaires at various points. We have clearly outlined the study procedure in the information sheet, which you will find enclosed.

The information you give us in the questionnaire will be looked at only by the stoma team and psychology service involved in this audit. Your data will be stored securely. Any written report or presentation of the findings will not include identifiable information of those who took part.
If you have any questions, please do not hesitate to contact your stoma nurse.

Thank you very much for your time reading this and for considering your participation.

With best wishes,

Stoma nurse team & psychology service

Patients first • Personal responsibility • Passion for excellence • Pride in our team

APPENDIX 7 INFORMATION SHEET AND CONSENT FORM

Department of Psychology
Royal Holloway, University of London
Egham, Surrey TW20 0EX
www.royalholloway.ac.uk/psychology

+44 (0) 1784 443526
PSY-enquiries@rhul.ac.uk

Information Sheet
Study: Adjustment in stoma patients

My name is Simone Raenker and I am a trainee clinical psychologist studying for a doctorate in clinical psychology at Royal Holloway, University of London. I am carrying out a study on adjustment in patients undergoing stoma surgery, supervised by Dr. Abigail Wroe. This research project is part of my course assignments and data will be used for writing a thesis on the topic.
If you would like to discuss any aspect of the research with Dr. Abigail Wroe, you can contact her by email Abigail.wroe@rhul.ac.uk. If you need to contact me, please email simone.raenker.2011@live.rhul.ac.uk or call 01784 443851.

I would very much appreciate your participation, because it would help us to enhance the understanding of the experience stoma patients go through, how the operation and living with a stoma impact on their well-being, and how health care professionals can provide support to patients.

Who should be involved in the project?

We would like to invite men and women who are undergoing surgery that may result in a stoma (planned or emergency surgery) or who had stoma surgery in the past 12 months.

What is the purpose of this project?

The purpose of this study is to investigate how patients cope with having a stoma. We want to find out about the thoughts and feelings people experience and the affects on them. It is also of interest to examine possible difference in people who are having a planned versus emergency stoma surgery.

The results of this study are intended to be used to inform clinicians and everyone involved in the care of someone with a stoma, how they can best support this person and meet their needs for advice and help.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason without prejudicing your present care. All the data you have provided would also be removed from our database and files unless it has been assigned an anonymous numeric code after which time we will not be able to remove the data. If you choose not to take part, your present care will not be affected. You can also choose not to complete all the questions in the assessment.

What will happen if I agree to take part?

Your stoma nurse has informed you about this study. Simone will get in contact with you by phone after sending the information sheet, consent form, and first set of questionnaire for your reference. You can clarify any points that are unclear during this telephone conversation.

If you agree to take part, we would kindly ask you to complete a questionnaire, which will take between 30 – 45 minutes. You can complete this questionnaire on your own or with Simone together on the phone. Please let us know your preferred options.

NRES ethical approval number: 14/NW/1286
Version 2
Psychology Department Ethics Committee, Royal Holloway, University of London. 10 April 2014

We hope to be able to talk to you before your surgery, 4 – 6 weeks after your operations and may ask you to complete the questionnaire again after some time (i.e. 3 after your surgery). You can withdraw from the study at any point without giving any reasons.

Are there any risks?

You will answer questions about your feelings and thoughts in regards to your general life context and in relation to your operation and how you are coping with the stoma. We are very aware that these are sensitive topics and it is possible that you experience distress. Should you feel uncomfortable or upset during the assessment, you can continue the assessment at a different time. Should you consent to it, we will help to facilitate contact to your clinical team, who will be able to offer in-depth support for you.

Possible benefits

Your participation serves as an exploratory approach to improve service provision for patients with a stoma. By participating in this study, you will help to gather information that enhance the understanding of the experiences of patients undergoing stoma surgery. These findings will be used to formulate your needs for support and advice and how services can provide this effectively. We hope that you will find your participation empowering.

Arrangements for ensuring anonymity and confidentiality

All information that you provide during the course of the research will be kept strictly confidential. The information will be made anonymous (any identifiable details such as name and address removed). Confidential information will only be accessible to authorised people (i.e. members of staff employed on the project). All information you provide will be identified by a numeric code. If any publication results from this research, you will not be identified by name. Confidentiality might be breached if a person discloses information that poses a risk to self or to others (particularly if significant risk of harm to a child).

Please keep this part of the sheet yourself for reference. Please feel free to ask any questions before you complete the consent form below, then tear off and hand the completed consent form to the researcher. It will be stored separately from the anonymous information you provide for the research project. This study has been reviewed and approved by the Psychology Department internal ethical procedure at Royal Holloway, University of London.

✂.....

Consent form ID number.....

Study: Adjustment in stoma patients

You have been asked to participate in a study about (fill in here), which is being carried out by Simone Raenker. Have you (please circle yes or no):

Read the information sheet about the study? yes no

Had an opportunity to ask questions? yes no

Got satisfactory answers to your questions? yes no

Understood that you're free to withdraw from the study at any time, without giving a reason (and without it affecting your care/ education if applicable)? yes no

Do you agree to take part in the study ? yes no

Signature _____

Name in block letters _____

Date _____

NB: This consent form will be stored separately from the anonymous information you provide.

NRES ethical approval number: 14/NW/1286
Version 2
Psychology Department Ethics Committee, Royal Holloway, University of London. 10 April 2014

APPENDIX 8 SHORT STUDY INFORMATION AND CONTACT DETAILS TO BE USED BY STOMA NURSES FOR RECRUITMENT

Department of Psychology **Doctorate in Clinical Psychology**

Study: Adjustment to stoma surgery

Short Information Sheet and Contact Details of Participants

Objective and procedure of the study:

This study investigates how patients cope with surgery that may result in a stoma.

Participants will be asked to complete a questionnaire with the researcher before undergoing surgery, shortly after, and 3 months after the operation. Some patients may be approached after their operation and complete one set of questionnaires shortly after their surgery.

This study aims to increase the understanding of what it means to patients to go through an operation that may result in a stoma. The results of this study will be used to inform clinical practice. For example, we hope to conclude from the research findings how patients can be supported before and after their surgery by the clinical team in order to address their needs and foster well-being and reduce stress.

The National Research Ethic Service and the Royal Holloway University of London ethic committee have approved this study. Data are treated anonymously (i.e. participants will receive a unique code) and patients can withdraw from taking part in this research project at any given point.

Please provide the clinical staff with your contact details if you are interested in hearing more about the study. The researcher, Dr. Simone Raenker, will be in contact with you shortly. If you wish so, you can *contact Simone on 01784 443851 or email simone.raenker.2011@live.rhul.ac.uk.*

Your help is much appreciated!

XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX

Study "Adjustment to stoma surgery"

I agree to be contacted by the research team.

Date ..... Name ..... Signature .....

Patient contact details (in block capitals please):

Name	
Address	
Phone No.	
Email	

Please fax to 01784 472746; please address fax to Simone Raenker

APPENDIX 9 STUDY QUESTIONNAIRE – DEMOGRAPHIC ITEMS AND STOMA QUESTIONNAIRE

Study: Adjustment to stoma surgery

Questionnaire

Participants ID:

The information that you give us in this questionnaire will be treated as strictly confidential and will be used to help us address issues that are important to patients undergoing surgery that might result in a stoma.

Demographic Questionnaire

What is your gender?

❑ Male ❑ Female

What is your date of birth?

……../……../……

How old are you?

……

What is your most recent or current occupation?

……

What is your employment status?

❑ Full time ❑ Retired

❑ Part time ❑ Sick leave

❑ Unemployed ❑ House wife / husband

❑ Student

❑ Other ……(please specify)

What is your highest level of education?

❑ No qualifications ❑ University Degree

❑ O Level / GCSE ❑ Postgraduate Degree

❑ A Level / NVQ ❑ Diploma / BTEC

❑ Other……(please specify)

What is your marital status?

- ❑ Married
- ❑ Divorced
- ❑ Living together
- ❑ Separated
- ❑ Single
- ❑ Widowed

What is your ethnicity?

(a) WHITE

- ☐ British
- ☐ Irish
- ☐ Any other White background *please write in below* .....

(b) BLACK or BLACK BRITISH

- ☐ Caribbean
- ☐ African
- ☐ Any other Black background *please write in below*.....

(c) ASIAN or ASIAN BRITISH

- ☐ Indian
- ☐ Pakistani
- ☐ Bangladeshi
- ☐ Any other Asian background *please write in below*.....

(d) MIXED

- ☐ White and Black Caribbean
- ☐ White and Black African
- ☐ White and Asian
- ☐ Any other Mixed background *please write in below*.....

Medical questionnaire

What is your most recent medical diagnosis? ❑ Cancer ❑ Benign ❑ Other, please specify. ……
Was your surgery planned or an emergency? ❑ Planned ❑ Emergency Date of last stoma surgery: _____ Did your operation result in a stoma? ❑ Yes ❑ No Yes your stoma been reversed since your operation? ❑ Yes ❑ No If yes, when was the reversal done? Date _____
For how long have you been suffering from the condition that has led to the stoma surgery? …… months, years
Any other information:

Stoma questionnaire (adapted from Wroe et al. 2003 and Salkovskis et al. 2004)

Please circle your answer.

How much do you feel that you were involved in the decision around having surgery that result in a stoma? Very dissatisfied .....Very Satisfied **1 2 3 4 5 6 7 8 9 10**
How much information do you feel you have been given about why you need to have a stoma? Very dissatisfied .....Very Satisfied **1 2 3 4 5 6 7 8 9 10**
How much information do you feel you have been given about how to look after your stoma? Very dissatisfied .....Very Satisfied **1 2 3 4 5 6 7 8 9 10**
How well do you feel prepared for the negative aspects (physical) of having a stoma based on the information you received? Very dissatisfied .....Very Satisfied **1 2 3 4 5 6 7 8 9 10**

How well do you feel prepared for the negative aspects (psychological) of having a stoma based on the information you received? Very dissatisfied .....Very Satisfied **1 2 3 4 5 6 7 8 9 10**
Do you feel you received overall the appropriate amount of information of how to live with a stoma? Very dissatisfied .....Very Satisfied **1 2 3 4 5 6 7 8 9 10**
How burdensome do you experience your physical symptoms (prior your stoma surgery)? Very burdensome.....Not burdensome at all **1 2 3 4 5 6 7 8 9 10**

APPENDIX 10 HOSPITAL ANXIETY AND STRESS SCALE (ZIGMOND & SNAITH, 1983)

Hospital Anxiety and Depression Scale (HADS)

Tick the box beside the reply that is closest to how you have been feeling in the past week.
Don't take too long over you replies: your immediate is best.

D	A		D	A	
		I feel tense or 'wound up':			**I feel as if I am slowed down:**
	3	Most of the time	3		Nearly all the time
	2	A lot of the time	2		Very often
	1	From time to time, occasionally	1		Sometimes
	0	Not at all	0		Not at all
		I still enjoy the things I used to enjoy:			**I get a sort of frightened feeling like 'butterflies' in the stomach:**
0		Definitely as much		0	Not at all
1		Not quite so much		1	Occasionally
2		Only a little		2	Quite Often
3		Hardly at all		3	Very Often
		I get a sort of frightened feeling as if something awful is about to happen:			**I have lost interest in my appearance:**
	3	Very definitely and quite badly	3		Definitely
	2	Yes, but not too badly	2		I don't take as much care as I should
	1	A little, but it doesn't worry me	1		I may not take quite as much care
	0	Not at all	0		I take just as much care as ever
		I can laugh and see the funny side of things:			**I feel restless as I have to be on the move:**
0		As much as I always could		3	Very much indeed
1		Not quite so much now		2	Quite a lot
2		Definitely not so much now		1	Not very much
3		Not at all		0	Not at all
		Worrying thoughts go through my mind:			**I look forward with enjoyment to things:**
	3	A great deal of the time	0		As much as I ever did
	2	A lot of the time	1		Rather less than I used to
	1	From time to time, but not too often	2		Definitely less than I used to
	0	Only occasionally	3		Hardly at all
		I feel cheerful:			**I get sudden feelings of panic:**
3		Not at all		3	Very often indeed
2		Not often		2	Quite often
1		Sometimes		1	Not very often
0		Most of the time		0	Not at all
		I can sit at ease and feel relaxed:			**I can enjoy a good book or radio or TV program:**
	0	Definitely	0		Often
	1	Usually	1		Sometimes
	2	Not Often	2		Not often
	3	Not at all	3		Very seldom

Please check you have answered all the questions

Scoring:
Total score: Depression (D) _____ Anxiety (A) _____
0-7 = Normal
8-10 = Borderline abnormal (borderline case)
11-21 = Abnormal (case)

APPENDIX 11 OSTONOMY ADJUSTMENT INVENTORY (SIMMONS ET AL. 2009)

OSTOMATES' ADJUSTMENT INVENTORY (OAI-23)

The statements below relate to how you feel about your stoma. For each statement please insert a ✔ in one of the boxes, "Strongly Agree" to "Strongly Disagree" to indicate your agreement with the statement. Please try to answer all of the questions.

	Strongly agree	Agree	Unsure	Disagree	Strongly Disagree
1. I feel that I have recovered from my stoma operation					
2. I don't like to touch or see my stoma					
3. I have a meaningful life even with a stoma					
4. I enjoy food and drinks as much as I did before my stoma					
5. My stoma inhibits me from having a proper bath or shower					
6. I sleep well without worrying about my stoma					
7. Because of my stoma I feel I am no longer in control of my life					
8. I am reluctant to mix socially since having my stoma					
9. I have now accepted my stoma as part of my body					
10. I cannot get over the shock of having a stoma					
11. Because of my stoma I limit my range of activities					
12. Because of my stoma I feel that I will always be a patient					
13. I am always conscious that my stoma may leak, smell or be noisy					
14. I have accepted the changes in my appearance which were caused by the stoma.					
15. I am grateful that the stoma has given me a new lease of life					
16. Caring for my stoma is difficult					
17. I feel that I am less sexually attractive because of my stoma					
18. I feel angry about having a stoma					
19. Despite my stoma I feel I have a rewarding life					
20. I will be able to manage my stoma in the future					
21. I am always anxious about my stoma					
22. With my stoma I feel that my life-threatening experience has passed					
23. I can engage in a variety of activities despite having a stoma					

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APPENDIX 12 SHORT HEALTH ANXIETY INVENTORY (SALKOVSKIS ET AL. 2002)

SHORT MONTH Ass / Wk / Sess: _____

HAI

Each question is this section consists of a group of four statements. Please read each group of statements carefully and then select the one which best describes your feelings, OVER THE PAST SIX MONTHS. Identify the statement by ringing the letter next to it ie. if you think that statement (a) is correct, ring statement (a); it may be that more than one statement applies, in which case, please ring any that are applicable.

1. a. I do not worry about my health.
   b. I occasionally worry about my health.
   c. I spend much of my time worrying about my health.
   d. I spend most of my time worrying about my health.

2. a. I notice aches/pains less than most other people (of my age).
   b. I notice aches/pains as much as most other people (of my age).
   c. I notice aches/pains more than most other people (of my age).
   d. I am aware of aches/pains in my body all the time.

3. a. As a rule I am not aware of bodily sensations or changes.
   b. Sometimes I am aware of bodily sensations or changes.
   c. I am often aware of bodily sensations or changes.
   d. I am constantly aware of bodily sensations or changes.

4. a. Resisting thoughts of illness is never a problem.
   b. Most of the time I can resist thoughts of illness.
   c. I try to resist thoughts of illness but am often unable to do so.
   d. Thoughts of illness are so strong that I no longer even try to resist them.

5. a. As a rule I am not afraid that I have a serious illness.
   b. I am sometimes afraid that I have a serious illness.
   c. I am often afraid that I have a serious illness.
   d. I am always afraid that I have a serious illness.

6. a. I do not have images (mental pictures) of myself being ill.
   b. I occasionally have images of myself being ill.
   c. I frequently have images of myself being ill.
   d. I constantly have images of myself being ill.

7. a. I do not have any difficulty taking my mind off thoughts about my health.
   b. I sometimes have any difficulty taking my mind off thoughts about my health.
   c. I often have any difficulty taking my mind off thoughts about my health.
   d. Nothing can tame my mind off thoughts about my health.

8. a. I am lastingly relieved if my doctor tells me there is nothing wrong.
   b. I am initially relieved but the worries sometimes return later.
   c. I am initially relieved but the worries always return later.
   d. I am not relieved if my doctor tells me there is nothing wrong.

9. a. If I hear about an illness I never think I have it myself.
   b. If I hear about an illness I sometimes think I have it myself.
   c. If I hear about an illness I often think I have it myself.
   d. If I hear about an illness I always think I have it myself.

10. a. If I have a bodily sensation or change I rarely wonder what it means.
    b. If I have a bodily sensation or change I often wonder what it means.
    c. If I have a bodily sensation or change I always wonder what it means.
    d. If I have a bodily sensation or change I must know what it means.

11. a. I usually feel at very low risk for developing a serious illness.
    b. I usually feel at fairly low risk for developing a serious illness.
    c. I usually feel at moderate risk for developing a serious illness.
    d. I usually feel at high risk for developing a serious illness.

12. a. I never think I have a serious illness.
    b. I sometimes think I have a serious illness.
    c. I often think I have a serious illness.
    d. I usually think that I am seriously ill.

13. a. If I notice an unexplained bodily sensation I never do anything to try to get rid of it.
    b. If I notice an unexplained bodily sensation I sometimes try to get rid of it.
    c. If I notice an unexplained bodily sensation I often try to get rid of it.
    d. If I notice an unexplained bodily sensation I always try to get rid of it.

14. a. My family/friends would say I do not worry enough about my health.
    b. My family/friends would say I have a normal attitude to my health.
    c. My family/friends would say I worry too much about my health.
    d. My family/friends would say I am a hypochondriac.

For the following questions, please think about what it might be like if you had a serious illness of a type which particularly concerns you (such as heart disease, cancer, multiple sclerosis and so on). Obviously you cannot know for definite what it would be like; please give your best estimate of what you <u>think</u> might happen, basing your estimate on what you know about yourself and serious illness in general.

15. a. If I had a serious illness I would still be able to enjoy things in my life quite a lot.
    b. If I had a serious illness I would still be able to enjoy things in my life a little.
    c. If I had a serious illness I would be almost completely unable to enjoy things in my life.
    d. If I had a serious illness I would be completely unable to enjoy life at all.

16. a. If I developed a serious illness there is a good chance that modern medicine would be able to cure me.
    b. If I developed a serious illness there is a moderate chance that modern medicine would be able to cure me.
    c. If I developed a serious illness there is a very small chance that modern medicine would be able to cure me.
    d. If I developed a serious illness there is no chance that modern medicine would be able to cure me.

17. a. A serious illness would ruin some aspects of my life.
    b. A serious illness would ruin many aspects of my life.
    c. A serious illness would ruin almost every aspect of my life.
    d. A serious illness would ruin every aspect of my life.

18. a. If I had a serious illness I would not feel that I had lost my dignity.
    b. If I had a serious illness I would feel that I had lost a little of my dignity.
    c. If I had a serious illness I would feel that I had lost quite a lot of my dignity.
    d. If I had a serious illness I would feel that I had totally lost my dignity.

APPENDIX 12 STOMA SELF-EFFICACY SCALE (BEKKERS ET AL., 1996)

Subject ID:_____

STOMA SELF-EFFICACY SCALE

(BEKKERS ET AL. 1996)

Mark an X in the column that indicates how confident you feel in response to each item.

	Not confident	Slightly confident	Fairly confident	Highly confident	Extremely confident
1. *Apply the stoma collection materials before leakage appear?*					
2. *Prevent having a leakage?*					
3. *Take care of the stoma in the right way at home?*					
4. *Prevent having skin problems?*					
5. *Prevent having stoma bleeding and damage?*					
6. *Apply the stoma collection materials in the way you learned to do?*					
7. *Prevent having obstruction?*					
8. *Follow the WOC nurse's instructions for handling the stoma?*					

9. *Follow the doctor's advice for taking care of your stoma and nutrition pattern?*					
10. *Take care of the stoma in the right way outdoors?*					
11. *Take care of the stoma when you are ill?*					
12. *Wear most of the clothes you like?*					
13. *Carry out light duties in and around the house (i.e. washing up, gardening)?*					
14. *Make new friends and acquaintances?*					
15. *Travel by train or bus?*					
16. *Tell your close friends about the stoma?*					
17. *Tell other people about the stoma?*					
18. *Go out shopping and visit people?*					
19. *Go out to a restaurant, café, or cinema the way you did before you were ill?*					
20. *Sleep away from home ate a friend's house where they know about the stoma?*					

21. *Sleep away from home ate a friend's house where they do not know about the stoma?*					
22. *Go on holidays (just like you did before the illness)?*					